

Additional Case Law, Code & Exhibits

I. 5th Circuit Antitrust and Sherman Act Case Law

MM Steel, LP v. Reliance Steel & Aluminum Co. et al, No. 4:2012cv01227 - Document 504
(S.D. Tex. 2014)

2 Companies conspiring against Competitor(s)

Tunica Web Advertising v. TUNICA CASINO OPERATORS, 496 F.3d 403 (5th Cir. 2007)
Section 1 of the Sherman Act

Spectators' Comm. Network, Inc. v. Colonial Country Club, et al., 253 F.3d 215 (5th Cir. 2001)

1. *Engaged in Conspiracy;*
2. *That restrained trade;*
3. *In a particular market*

NW Wholesale Stationers v. Pac. Stationery 472 U.S. 284 (1985)

"Disadvantage competitors by directly denying... relationships the competitor needs in the competitive struggle"

II. DEA Antitrust Statement by the DOJ

UNITED STATES DEPARTMENT OF JUSTICE DRUG ENFORCEMENT ADMINISTRATION

_____		Docket Number
In the Matter of		99-27
JOHNSON MATTHEY, INC.		

**MEMORANDUM OF THE ANTITRUST DIVISION OF THE UNITED STATES
DEPARTMENT OF JUSTICE AS AMICUS CURIAE IN SUPPORT
OF THE APPLICATION OF JOHNSON MATTHEY, INC.**

Competition is a rough, often inelegant process by which winners and losers -- whether products, firms, or technologies -- are chosen by decisions made in the marketplace. In that process, economic actors are constantly challenged to improve on price, cost, and technology -- or exit. The end result is economic efficiency and increased technological innovation. Properly understood, the various challenges to the application of Johnson Matthey, Inc. ("Johnson Matthey") raised by Mallinckrodt, Inc. ("Mallinckrodt") and Noramco of Delaware, Inc. ("Noramco") rest on one ground: their fervid desire to avoid such competition and the challenges it would pose to them. Should their efforts to block Johnson Matthey's entry into the market succeed, the result will almost certainly be a less efficient and less innovative market and, ultimately, higher prices for consumers.

For that reason, assuming that the DEA can appropriately regulate Johnson Matthey's facilities to avoid illegal diversion, the Antitrust Division (the "Division") supports this application for registration.⁽¹⁾ **More importantly, the Division strongly recommends that the DEA avail itself of this opportunity to clarify yet again its commitment to competition by lowering the regulatory barriers to entry consistent with the need to prevent unlawful diversion. As discussed below, where a market cannot sustain numerous participants -- whether because of production requirements, economies of scale, or government regulation -- its competitiveness depends significantly on facilitating the potential for entry.** By clearly articulating the appropriate standard to be used in these proceedings, and by placing the burden of proof where it properly belongs, the DEA will be able to discourage the continuing use of its procedures by those who seek to hinder the development of competition

Noramco of Delaware, Inc., Petitioner, v. Drug Enforcement Administration,
Respondent.johnson Matthey, Inc., Intervenor.noramco of Delaware, Inc., Petitioner, v. Drug
Enforcement Administration, Respondent.penick Corporation, Inc. and Mallinckrodt, Inc.,
Intervenor, 375 F.3d 1148 (D.C. Cir. 2004)

Noramco of Delaware, Inc. (Noramco) has filed two petitions for review of final orders of the Drug Enforcement Agency (DEA, Agency) which grant applications by Johnson Matthey, Inc. (Johnson Matthey) and by Penick Corporation, Inc. (Penick) to register as importers of narcotic raw materials (NRMs) pursuant to the Controlled Substances Import and Export Act, 21 U.S.C.

§§ 952 and 958, and the Controlled Substances Act, 21 U.S.C. §§ 823 et seq., (collectively referred to as CSA). For the reasons set out below, we deny both of Noramco's petitions.

The CSA establishes a comprehensive regulatory system that controls the manufacture, distribution and use of hazardous drugs. MD Pharm., Inc. v. DEA, 133 F.3d 8, 10 (D.C. Cir. 1998). The DEA Administrator, by delegation of the United States Attorney General, 28 C.F.R. § 0.100(b), classifies each drug into one of five schedules according to such factors as its potential for abuse and its risk to the public health Id. (citing 21 U.S.C. § 811).¹ In order to import or export a controlled substance, a company must apply for and obtain registration with

the DEA, 21 U.S.C. § 957, which is required to register an application for Schedule I or II substances if it "determines that such registration is consistent with the public interest and with United States obligations under international treaties, conventions, or protocols in effect on May 1, 1971," 21 U.S.C. § 958(a). Section 823(a) of title 21 sets out the factors to be considered in determining the public interest: (1) "maintenance of effective controls against diversion of [controlled substances and their compounds] into other than legitimate medical, scientific, research, or industrial channels, by limiting the importation and bulk manufacture of such controlled substances to a number of establishments which can produce an adequate and uninterrupted supply of these substances under adequately competitive conditions for legitimate medical, scientific, research, and industrial purposes"; (2) "compliance with applicable State and local law"; (3) "promotion of technical advances in the art of manufacturing these substances and the development of new substances"; (4) the "prior conviction record of [the] applicant under Federal and State laws relating to the manufacture, distribution, or dispensing of such substances"; (5) "past experience in the manufacture of controlled substances, and the existence in the establishment of effective control against diversion"; and (6) "such other factors as may be relevant to and consistent with the public health and safety." Pursuant to these provisions, both Johnson Matthey and Penick filed applications with the DEA for registration. Before filing its registration application, Johnson Matthey was already registered as an importer of phenyl acetone, a Schedule II controlled substance, and as a bulk manufacturer of Schedule I and II substances, including oxycodone and hydrocodone, which are active pharmaceutical ingredients (APIs) that it sells in bulk to manufacturers of narcotic-based prescription drugs. Because Johnson Matthey was not registered to import opium or poppy straw concentrate, the NRMs from which the narcotic alkaloids morphine, codeine and thebaine are extracted to produce oxycodone and hydrocodone, it had to rely on supplies from Noramco and Mallinckrodt, Inc. (Mallinckrodt), the two companies then registered to import the NRMs. Dissatisfied with this arrangement, on December 23, 1998 it filed an application to modify its registration to include importation of opium and poppy straw concentrate. At the same time it applied to renew its registration to manufacture Schedule I and II controlled substances in bulk. On May 10, 1999 Noramco and Mallinckrodt filed separate objections to and requests for hearing on Johnson Matthey's registration application.

An administrative law judge (ALJ) conducted a hearing in January 2000. In a decision filed September 21, 2000 the ALJ recommended that Johnson Matthey's application be granted, subject to the conditions that Johnson Matthey (1) demonstrate to the DEA's satisfaction, before receipt of its first NRM shipment, "the manner in which the NRMs will be imported, transferred to the processing facility, and processed," (2) provide the DEA with a timetable for its proposed "ramp-up activities" and (3) inform the DEA of "any changes to these procedures and/or any changes made to the physical plant" and obtain approval thereof before making any shipment under the "changed circumstances." Johnson Matthey, Inc., Docket No. 99-27 (September 21, 2000) ("Recommended Rulings, Findings of Fact, Conclusions of Law, and Decision") (ALJ Op. I), slip op. at 57.

In a decision dated May 22, 2002 the DEA Deputy Administrator adopted and incorporated the ALJ's findings and conclusions "in their entirety" and granted Johnson Matthey "a conditional registration until such time as Johnson Matthey's facilities are complete and DEA can complete

its requisite physical security and record keeping evaluation to ensure Johnson Matthey's continued protection of NRMs against diversion." Johnson Matthey, Inc., 67 Fed.Reg. 39,041, 39,045 (June 6, 2002) (conditional grant of registration to import Schedule II substances). The decision further directed that "Johnson Matthey should provide DEA with a timetable of its proposed activities and submissions so that DEA may plan for the prompt scheduling of its inspection and review activities." Id. at 39,045-46.

Penick filed its application on April 11, 2000 for registration to import the Schedule II NRMs coca leaves, raw opium, poppy straw and poppy straw concentrate and to manufacture Schedule II APIs, including oxycodone, hydrocodone, morphine, hydromorphone and codeine, from the imported NRMs. On September 15, 2000 Noramco and Mallinckrodt each filed objections to and requests for hearing on Penick's registration application.

An ALJ conducted a hearing on Penick's application in July and August 2001. In a decision filed May 29, 2002 the ALJ recommended that Penick's application be granted. Penick Corp., Docket No. 01-3 (May 29, 2002) ("Opinion and Recommended Ruling, Findings of Fact, Conclusions of Law and Decision of the Administrative Law Judge") (ALJ Op. II). On February 11, 2003, the DEA Deputy Administrator issued a final order adopting the ALJ's findings and conclusions "in their entirety." Penick Corp., Inc., 68 Fed.Reg. 6947, 6948 (Feb. 11, 2003) (grant of registration to import Schedule II substances).

Noramco filed a timely petition for review of each registration approval. Mallinckrodt intervened in the challenge to Penick's registration. We address each registration separately.

Noramco challenges the DEA's conditional grant of Johnson Matthey's registration application on two grounds: (1) the DEA misconstrued its obligation to ensure effective diversion control under section 823(a) and (2) the DEA acted arbitrarily and capriciously in failing to require Johnson Matthey to submit detailed plans for importing NRMs and processing them into APIs.

We find neither ground meritorious.

First, Noramco contends the DEA's approval of Johnson Matthey's registration contravenes the plain language of section 823(a) (1). We review the DEA's interpretation of section 823 under the familiar two-step Chevron framework:

We first ask "whether Congress has directly spoken to the precise question at issue," in which case we "must give effect to the unambiguously expressed intent of Congress." If the "statute is silent or ambiguous with respect to the specific issue," however, we move to the second step and defer to the agency's interpretation as long as it is "based on a permissible construction of the statute."

Bluewater Network v. EPA, 372 F.3d 404, 410 (D.C. Cir. 2004) (quoting Chevron U.S.A. Inc. v. Natural Res. Def. Council, [467 U.S. 837](#), 842-43, 104 S. Ct. 2778, 2781, 81 L. Ed. 2d 694 (1984)). Noramco contends that under Chevron step one, the unambiguous language of section 823(a) (1) requires that, before the DEA approves an application for registration to import a Schedule I or II controlled substance, the agency is required to balance the risk of unlawful diversion of the substance against the need for competition by ensuring both (1) that effective controls will be maintained against diversion and (2) that approval will not increase the number of importers beyond that which can "produce an adequate and uninterrupted supply of these substances under adequately competitive conditions for legitimate ... purposes," 21 U.S.C. § 823(a) (1). We disagree.

Section 823(a) (1) does not expressly speak to whether the DEA must consider the number of importers necessary to provide an adequate supply if it determines diversion will be effectively controlled regardless. The stated purpose of section 823(a) (1) is to effectively control against diversion and it expressly directs the DEA to limit competition only as a means to achieve "maintenance" of such control. In the absence of an express contrary statutory directive, the DEA reasonably concluded under Chevron step 2 that "if DEA determines that there would be no increased difficulty in controlling diversion, the requirements of [section 823(a) (1)] are satisfied, and an analysis of adequate competition is not required." 67 Fed.Reg. at 39,044; see also *id.* at 39,043-44 ("Furthermore, DEA has written that, stated conversely, DEA is `required to register an applicant who meets all the other statutory requirements, without regard to the adequacy of competition, if the Administration determines that registering another manufacturer will not increase the difficulty of maintaining effective controls against diversion.'" (quoting Bulk Manufacture of Schedule I and II Substance, 39 Fed.Reg. 12,138 (DEA April 13, 1974)).² The DEA determined, based on substantial expert testimony, that Johnson Matthey's registration is consistent with section 823(a) (1) because it found that "Johnson Matthey is in compliance with DEA regulations" and "maintain [s] effective controls against diversion of controlled substances," 67 Fed. Reg. at 39,044-45 — findings that Noramco does not dispute, see *Pet'r Br.* (02-1211) at 24. After analyzing the other five statutory factors, the DEA concluded that registration is in the public interest based on findings that Johnson Matthey's registration (1) "promote [s] technical advances in the manufacturing of oxycodone and hydrocodone" because Johnson Matthey had obtained or applied for 6 patents to more efficiently produce APIs and (2) helps ensure a steady supply of APIs and pharmaceuticals. 67 Fed.Reg. at 39,045, ALJ Op. I at 16-17. Thus, under the DEA's permissible interpretation of section 823(a), it was required to approve Johnson Matthey's registration. Noramco challenges the DEA's reading of section 823(a) (1) on two grounds. First, Noramco charges that the DEA's interpretation ignores the distinction between the statutory regulation of Schedule I and II substances, at issue here, and of Schedule III and IV substances. Noramco points out that section 823(d), which governs Schedule III and IV substances, lists the same six public interest factors as section 823(a) — except that the first factor in 823(d) (1) lacks the limiting prepositional phrase addressing supply and competition contained in section 823(a) (1) ("by limiting the importation and bulk manufacture of such controlled substances to a number of establishments which can produce an adequate and uninterrupted supply of these substances under adequately competitive conditions for legitimate medical, scientific, research, and industrial purposes"). The DEA's interpretation, Noramco argues, "eviscerates" this distinction by eliminating the competition factor from the public interest calculus. Not so. Under the DEA's interpretation, it must still ensure that the number of importers and manufacturers is limited where such limitation is necessary to maintain effective diversion controls; it is only where, as here, the DEA affirmatively finds that diversion will be effectively controlled without regard to limiting competition that it is not required to inquire into market competitiveness.

Second, Noramco contends the DEA's interpretation is inconsistent with the CSA's legislative history and with the testimony before the ALJ by a former DEA administrator. The statements Noramco cites, however, simply reflect a concern that the marketing of Schedule I and II controlled substances not be so broadened as to enhance the risk of diversion. See *Pet'r Br.*

(02-1211) at 42-44 (quoting S.Rep. No. 91-613 at 7 (1969) (explaining that section 823(a) (1) addresses "concern ... that parts of [the CSA] ... may tend to expand the commerce in controlled dangerous substances, particularly narcotics, possibly adding to the danger of diversion and leading to unfavorable changes in the price structures of these substances") (first ellipsis added); CSA, Hearings before the Subcomm. to Investigate Juvenile Delinquency of Sen. Comm. on the Judiciary, 91st Cong. 261-62 (1969) (Statement of Attorney Gen. Mitchell) ("[T]here is no intention on the part of the Justice Department nor the Bureau of Narcotics and Dangerous Drugs by this provision to expand beyond necessity ... any manufacturers in this particular area"); *id.* at 371 (Statement of Dep't of Justice) ("If evidence indicates that additional licensing will result in more reasonable prices with no significant diminution in the effectiveness of drug control, the Attorney General should be able to license the additional manufacturers."));

Pet'r Br. (02-1211) at 40 (quoting testimony of former DEA Administrator Peter Bensinger) ("Given the intent of the law and regulations to limit the number of registrants, in administering the law one must accept that not all qualified persons who seek to register are entitled to be registered.... The public interest is served by limiting the access to NRMS to a much smaller number of companies than would be appropriate in a free market."). That concern is not in play where, as here, the DEA affirmatively finds that diversion is effectively controlled.

Noramco next contends that the DEA acted arbitrarily and capriciously in not requiring that Johnson Matthey submit "concrete" plans for how it will import and process NRMs (specifically regarding the technology it will use, the amount and identity of NRMs imported, the kind of plant it will construct, the technical expertise of its employees and its commitment to spend sufficient funds). Noramco asserts that by failing to do so the DEA held Johnson Matthey to a "lower standard of proof" than it imposed when it granted the registration application of McNeilab, Inc. in 1981. Pet'r Br. (02-1211) 57. We see no material difference in the DEA's treatment of the two applicants. McNeilab's application was approved "contingent upon the successful completion of all necessary and pertinent actions outlined in the applications, such as the construction of a secure manufacturing facility, and upon the ultimate approval of those actions by the Drug Enforcement Administration." *McNeilab, Inc.*, 46 Fed.Reg. 22,089 (DEA Apr. 15, 1981) (grant of registration; adopting findings of fact and conclusions of law from *McNeilab, Inc.*, Docket No. 78-12 (Aug. 20, 1980)). This is substantially what the DEA did in approving Johnson Matthey's application "upon Johnson Matthey's providing to DEA, prior to the receipt of the first shipment of NRMs, sufficient information concerning its facilities and procedures contingent upon the successful completion of all necessary and pertinent actions outlined in the applications, such as the construction of a secure manufacturing facility, and upon the ultimate approval of those actions by the Drug Enforcement Administration." 67 Fed.Reg. at 39,045. In each case, the DEA withheld final approval pending the applicant's completion of its facilities and the DEA's ultimate approval thereof. Noramco complains in particular that the DEA did not require that Johnson Matthey, as McNeilab was required to do, provide a "concrete business plan calling for the importation of opium and the construction of a plant capable of converting opium into APIs."

Pet'r Br. (02-1211) at 58. Unlike McNeilab, however, Johnson Matthey was already in the business of importing and manufacturing controlled substances and had facilities in place for doing so. Given Johnson Matthey's experience and its pre-existing facilities, the DEA

*reasonably required less detailed specifications in advance of Jackson Matthey's proposed expansion.*³

Noramco and intervenor Mallinckrodt raise both statutory and evidentiary challenges to the DEA's approval of Penick's registration. We address, and reject, each of their arguments in turn.

*First, Noramco and Mallinckrodt assert the DEA misinterpreted section 823(a) (1) as not requiring it to consider the effect of Penick's registration on diversion overseas, specifically potential diversion in India, a primary source of imported NRMs.*⁴ *This argument fails for two reasons. First, the DEA in fact considered and rejected the contention that Penick's registration would increase diversion in India. Noramco argued before the agency that Penick's use of morphine-based technology was less efficient than Noramco's use of a high-thebaine-content poppy to produce oxycodone and would therefore increase demand, cultivation and production of opium in India and, in turn, the likelihood of diversion there. See JA 145-49 (Decl. of Noramco Vice President Michael Kindergan) (citing Decl. of Michael Wilson, Ph.D.). The ALJ found that "Noramco's and Mallinckrodt's claims that registering Penick would increase diversion in India are speculative at best, particularly in light of the as-yet-unknown impact of the expanded use of high-the-baine-content poppy straw as a narcotic raw material." ALJ Op. II at 94.*⁵ *We agree with the ALJ's assessment, especially in light of the testimony by Penick's research and development director that Penick could also manufacture oxycodone from high-thebaine poppy straw. See JA 997, 1004 (testimony of Bao-Shan Huang, Ph.D.) In any event, the DEA's alternate determination that it is not required to consider possible diversion overseas reflects a reasonable construction of section 823(a) (1) and we therefore uphold it under step two of Chevron.*

*As both the ALJ and the DEA noted, section 823(a) (1) is silent on whether the "diversion" the DEA must consider is limited to the United States or includes unlawful diversion overseas as well.*⁶ *Nonetheless, the language of the statute itself, in its focus on importation and domestic manufacturing, suggests, reasonably enough, that the Congress was concerned with preventing diversion in this country rather than abroad. The legislative history similarly suggests an intent to prevent diversion through control of commercial activities that occur in this country, rather than in the countries of origin. See Comprehensive Drug Abuse Prevention and Control Act of 1970, H. Rep. No. 91-1444 (Sept. 10, 1970), reprinted in 1970 U.S.C.C.A.N. 4566, 4571-72 ("The Bill is designed to improve the administration and regulation of the manufacturing, distribution, and dispensing of controlled substances by providing for a 'closed' system of drug distribution for legitimate handlers of such drugs. Such a closed system should significantly reduce the widespread diversion of these drugs out of legitimate channels into the illicit market. ..."). On the flip side, we find unpersuasive the authorities Noramco cites to support its assertion that "diversion," within the meaning of section 823(a) (1), is intended to include pre-importation diversion overseas. Neither the CSA's restrictions on limiting the United States' export of narcotics nor policies, unrelated to the CSA, that reflect concern over overseas diversion nor the testimony of a former DEA Administrator (cautioning against registering importers whose activities might adversely affect "the worldwide control, stability and supply of NRMs" or "the international drug control effort," Pet'r Br. at 03-1060) at 53 (quoting testimony of former Administrator Peter Bensinger)), negate the reasonableness of the DEA's construction of section 326(a) (1).*⁷

Next, Noramco and Mallinckrodt challenge the DEA's decision on a sufficiency of evidence ground. Under the CSA, the DEA's findings of fact, "if supported by substantial evidence, shall be conclusive." 21 U.S.C. § 877; see *MD Pharmaceutical, Inc. v. DEA*, 133 F.3d 8, 14 (D.C. Cir. 1998). We conclude that the challenged portions of the DEA's decision are supported by substantial evidence in the record.

Noramco and Mallinckrodt first assert that substantial evidence does not support the DEA's finding, in support of registration, that competition among NRM importers that process APIs is not adequate.⁸ See 21 U.S.C. § 823(a) (1) (directing DEA to consider "maintenance of effective controls against diversion of [controlled substances and their compounds] into other than legitimate medical, scientific, research, or industrial channels, by limiting the importation and bulk manufacture of such controlled substances to a number of establishments which can produce an adequate and uninterrupted supply of these substances under adequately competitive conditions for legitimate medical, scientific, research, and industrial purposes"). The ALJ concluded that competition was inadequate based on the undisputed evidence that "the prices of active pharmaceutical ingredients rose steeply from 1991 to 2000," concluding that "[t]his price increase, absent specific explanation, is strong evidence of a lack of competition in the active pharmaceutical ingredient market." ALJ Op. II at 92. The ALJ acknowledged that during the period there were a number of "switches" by purchasers from one of the bulk suppliers (Noramco and Mallinckrodt) to the other but concluded they "do not demonstrate strong competition."⁹ *Id.* Noramco and Mallinckrodt argue, as they did before the agency, that the price increases are attributable to rising costs of raw materials, rather than lack of competition, and cite their expert's testimony before the ALJ that their profit margins actually decreased between 1988 and 2000. The ALJ, however, found the increases in API prices and NRM costs "do not correlate strongly," *id.*, and this finding is supported by the evidence. Penick's expert economic witness, Michael I. Cragg, disputed the opinions of Noramco's and Mallinckrodt's experts, explaining they had compared apples with oranges. Cragg testified that the comparison of API prices and NRM costs "does not account for the relative importance of NRM inputs in overall costs" because "[a] kilogram of API and a kilogram of NRM are not comparable — the mistake is analogous to comparing the price of a gallon of gasoline to the price of a gallon of crude oil." JA 193 (Written Revised Direct Testimony of Michael I. Cragg, Ph.D.). The ALJ credited Cragg's testimony over the other experts', see ALJ Op. II at 89 ("[T]he two types of increases [costs of NRMs and prices of APIs] seem to be only loosely related when the proportion of the price of the active pharmaceutical ingredient that is attributable to the narcotic raw material is taken into consideration."), and our review of her choice among the "disputing expert witnesses" is "particularly deferential." *Fla. Mun. Power Agency v. FERC*, 315 F.3d 362, 368 (D.C. Cir. 2003) (quoting *Wis. Valley Improvement Co. v. FERC*, 236 F.3d 738, 746-47 (D.C. Cir. 2001)). Moreover, it is not surprising that profit margins declined somewhat after 1994 when Noramco joined Mallinckrodt in the market, transforming it from a monopoly to a duopoly — but this does not mean the minimal competition between two market participants was adequate. Noramco and Mallinckrodt also cite the evidence of customer switches between them as evidence of competition but, as the ALJ noted, citing Cragg's testimony, there was no evidence these switches were related to changes in API prices. Last, Noramco and Mallinckrodt assert that increased competition will not reduce the price of drugs to the consumer. This may

be true but expanding the playing field may yield other benefits such as reduced prices for bulk API purchasers and improved product quality, reliability of supply, financial terms and conditions and order lead times.

Finally, Noramco challenges the DEA's finding that Penick's registration will promote technical advances. Specifically, Noramco asserts that Penick's morphine-based production technology is less efficient than Noramco's high-thebaine poppy technology. This argument overlooks the substantial evidence that Penick has developed and patented numerous other processing technologies. See, e.g., JA 42-43, 72, 2384-85, 2696. Accordingly, we reject this argument as well.

*For the foregoing reasons, the petitions for review in these cases are denied.
So ordered.*

Extra Case Law

John Doe Inc v. DEA, 484 F.3d 561 (D.C. Cir. 2007)

Norman Bridge Drug Company, Plaintiff-appellee, v. Michael Banner, John R. Bartels, Jr., Administrator, Drug Enforcement Administration, et al., Defendants-appellants, 529 F.2d 822 (5th Cir. 1976)

III. RFRA Law

Burwell v. Hobby Lobby Stores, Inc. 573 U.S. ____ (2014)

“Following our decision in City of Boerne, Congress passed the Religious Land Use and Institutionalized Persons Act of 2000 (RLUIPA), 114Stat. 803, 42 U. S. C. §2000cc et seq. That statute, enacted under Congress’s Commerce and Spending Clause powers, imposes the same general test as RFRA but on a more limited category of governmental actions. See Cutter v. Wilkinson, 544 U. S. 709 –716 (2005). And, what is most relevant for present purposes, RLUIPA amended RFRA’s definition of the “exercise of religion.” See §2000bb–2(4) (importing RLUIPA definition). Before RLUIPA, RFRA’s definition made reference to the First Amendment. See §2000bb–2(4) (1994 ed.) (defining “exercise of religion” as “the exercise of religion under the First Amendment”). In RLUIPA, in an obvious effort to effect a complete separation from First Amendment case law, Congress deleted the reference to the First Amendment and defined the “exercise of religion” to include “any exercise of religion, whether or not compelled by, or central to, a system of religious belief.” §2000cc–5(7)(A). And Congress mandated that this concept “be construed in favor of a broad protection of

religious exercise, to the maximum extent permitted by the terms of this chapter and the Constitution.” §2000cc–3(g).

It held that the Greens’ businesses are “persons” under RFRA, and that the corporations had established a likelihood of success on their RFRA claim because the contraceptive mandate substantially burdened their exercise of religion...”

“Also rejected is the Government’s central submission that, because it has a compelling interest in the uniform application of the Controlled Substances Act, no exception to the DMT ban can be made to accommodate the UDV. The Government argues, inter alia, that the Act’s description of Schedule I substances as having “a high potential for abuse,” “no currently accepted medical use,” and “a lack of accepted safety for use . . . under medical supervision,” 21 U. S. C. §812(b)(1), by itself precludes any consideration of individualized exceptions, and that the Act’s “closed” regulatory system, which prohibits all use of controlled substances except as the Act itself authorizes, see Gonzales v. Raich, 545 U. S. ___, ___, cannot function properly if subjected to judicial exemptions. Pp. 8–16. (a) RFRA and its strict scrutiny test contemplate an inquiry more focused than the Government’s categorical approach. RFRA requires the Government to demonstrate that the compelling interest test is satisfied through application of the challenged law “to the person”—the particular claimant whose sincere exercise of religion is being substantially burdened. 42 U. S. C. §2000bb–1(b). Section 2000bb(b)(1) expressly adopted the compelling interest test of Sherbert v. Verner, 374 U. S. 398, and Wisconsin v. Yoder, 406 U. S. 205. There, the Court looked beyond broadly formulated interests justifying the general applicability of government mandates, scrutinized the asserted harms, and granted specific exemptions to particular religious claimants. Id., at 213, 221, 236; Sherbert, supra, at 410. Outside the Free Exercise

area as well, the Court has noted that “[c]ontext matters” in applying the compelling interest test, *Grutter v. Bollinger*, 539 U. S. 306, 327, and has emphasized that strict scrutiny’s fundamental purpose is to take “relevant differences” into account, *Adarand Constructors, Inc. v. Peña*, 515 U. S. 200, 228. Pp. 9–10. (b) Under RFRA’s more focused inquiry, the Government’s mere invocation of the general characteristics of Schedule I substances cannot carry the day. Although Schedule I substances such as DMT are exceptionally dangerous, see, e.g., *Touby v. United States*, 500 U. S. 160, 162, there is no indication that Congress, in classifying DMT, considered the harms posed by the particular use at issue.

...

Before the District Court, the Government also asserted an interest in compliance with the 1971 United Nations Convention on Psychotropic Substances, Feb. 21, 1971, [1979–1980], 32 U. S. T. 543, T. I. A. S. No. 9725. The Convention, signed by the United States and implemented by the Controlled Substances Act, calls on signatories to prohibit the use of hallucinogens, including DMT. The Government argues that it has a compelling interest in meeting its international obligations by complying with the Convention. The District Court rejected this interest because it found that the Convention does not cover hoasca. The court relied on the official commentary to the Convention, which notes that “Schedule I [of the Convention] does not list natural hallucinogenic materials,” and that “[p]lants as such are not, and it is submitted are also not likely to be, listed in Schedule I, but only some products obtained from plants.” U. N. Commentary on the Convention on Psychotropic Substances 387, 385 (1976). The court reasoned that hoasca, like the plants from which the tea is made, is sufficiently distinct from DMT itself to fall outside the treaty. See 282 F. Supp. 2d, at 1266–1269. We do not agree. The Convention provides that “a preparation is subject to the same measures of control as the psychotropic substance which it contains,” and defines “preparation” as “any solution or mixture, in whatever physical state, containing one or

more psychotropic substances.” See 32 U. S. T., at 546, Art. 1(f)(i); id., at 551, Art. 3. Hoasca is a “solution or mixture” containing DMT; the fact that it is made by the simple process of brewing plants in water, as opposed to some more advanced method, does not change that. To the extent the commentary suggests plants themselves are not covered by the Convention, that is of no moment—the UDV seeks to import and use a tea brewed from plants, not the plants themselves, and the tea plainly qualifies as a “preparation” under the Convention. The fact that hoasca is covered by the Convention, however, does not automatically mean that the Government has demonstrated a compelling interest in applying the Controlled Substances Act, which implements the Convention, to the UDV’s sacramental use of the tea.”

City of Boerne v. Flores⁵²¹ U.S. 507 (1997)

Congress enacted RFRA in direct response to the Court's decision in *Employment Div., Dept. of Human Resources of Ore. v. Smith*, [494 U. S. 872](#) (1990). There we considered a Free Exercise Clause claim brought by members of the Native American Church who were denied unemployment benefits when they lost their jobs because they had used peyote. Their practice was to ingest peyote for sacramental purposes, and they challenged an Oregon statute of general applicability which made use of the drug criminal. In evaluating the claim, we declined to apply the balancing test set forth in *Sherbert v. Verner*, [374 U. S. 398](#) (1963), under which we would have asked whether Oregon's prohibition substantially burdened a religious practice and, if it did, whether the burden was justified by a compelling government interest. We stated: "[G]overnment's ability to enforce generally applicable prohibitions of socially harmful conduct ... cannot depend on measuring the effects of a governmental action on a religious objector's spiritual development. To make an individual's obligation to obey such a law contingent upon the law's coincidence with his religious beliefs, except where the State's interest is 'compelling' ... contradicts both constitutional tradition and common sense." 494 U. S., at 885 (internal quotation marks and citations omitted).

The application of the *Sherbert* test, the *Smith* decision explained, would have produced an anomaly in the law, a constitutional right to ignore neutral laws of general applicability. The anomaly would have been accentuated, the Court reasoned, by the difficulty of determining whether a particular practice was central to an individual's religion. We explained, moreover, that it "is not within the judicial ken to question the centrality of particular beliefs or practices to a faith, or the validity of particular litigants' interpretations of those creeds." 494 U. S., at 887 (internal quotation marks and citation omitted).

The only instances where a neutral, generally applicable law had failed to pass constitutional muster, the *Smith* Court noted, were cases in which other constitutional protections were at stake. *Id.*, at 881-882. In *Wisconsin v. Yoder*, [406 U. S. 205](#) (1972), for example, we invalidated Wisconsin's mandatory school-attendance law as applied to Amish parents who refused on religious grounds to send their children to school. That case implicated not only the right to the free exercise of religion but also the right of parents to control their children's education. The *Smith* decision acknowledged the Court had employed the *Sherbert* test in considering free exercise challenges to state unemployment compensation rules on three occasions where the balance had tipped in favor of the individual. See *Sherbert*, *supra*; *Thomas v. Review Bd. of Indiana Employment Security Div.*, [450 U. S. 707](#) (1981); *Hobbie v. Unemployment Appeals Comm'n of Fla.*, [480 U. S. 136](#) (1987). Those cases, the Court explained, stand for "the proposition that where the State has in place a system of individual exemptions, it may not refuse to extend that system to cases of religious hardship without compelling reason." 494 U. S., at 884 (internal quotation marks omitted). By contrast, where a general prohibition, such as Oregon's, is at issue, "the sounder approach, and the approach in accord with the vast majority of our precedents, is to hold the test inapplicable to [free exercise] challenges." *Id.*, at 885. *Smith* held that neutral, generally applicable laws may be applied to religious practices even when not supported by a compelling governmental interest.

Four Members of the Court disagreed. They argued the law placed a substantial burden on the Native American Church members so that it could be upheld only if the law served a compelling state interest and was narrowly tailored to achieve that end. *Id.*, at 894. JUSTICE O'CONNOR concluded Oregon had satisfied the test, while Justice Blackmun, joined by Justice Brennan and Justice Marshall, could see no compelling interest justifying the law's application to the members.

These points of constitutional interpretation were debated by Members of Congress in hearings and floor debates. Many criticized the Court's reasoning, and this disagreement resulted in the passage of RFRA. Congress announced:

"(1) [T]he framers of the Constitution, recognizing free exercise of religion as an unalienable right, secured its protection in the First Amendment to the Constitution; "(2) laws 'neutral' toward religion may burden religious exercise as surely as laws intended to interfere with religious exercise;

"(3) governments should not substantially burden religious exercise without compelling justification;

"(4) in *Employment Division v. Smith*, [494 U. S. 872](#) (1990), the Supreme Court virtually eliminated the requirement that the government justify burdens on religious exercise imposed by laws neutral toward religion; and

"(5) the compelling interest test as set forth in prior Federal court rulings is a workable test for striking sensible balances between religious liberty and competing prior governmental interests." 42 U. S. C. § 2000bb(a).

The Act's stated purposes are:

"(1) to restore the compelling interest test as set forth in *Sherbert v. Verner*, [374 U. S. 398](#) (1963) and *Wisconsin v. Yoder*, [406 U. S. 205](#) (1972) and to guarantee its application in all cases where free exercise of religion is substantially burdened; and

"(2) to provide a claim or defense to persons whose religious exercise is substantially burdened by government." § 2000bb(b).

RFRA prohibits "[g]overnment" from "substantially burden[ing]" a person's exercise of religion even if the burden results from a rule of general applicability unless the government can demonstrate the burden "(1) is in furtherance of a compelling governmental interest; and (2) is the least restrictive means of furthering that compelling governmental interest." § 2000bb-1. The Act's mandate applies to any "branch, department, agency, instrumentality, and official (or other person acting under color of law) of the United States," as well as to any "State, or ... subdivision of a State." § 2000bb-2(1). The Act's universal coverage is confirmed in § 2000bb-3(a), under which RFRA "applies to all Federal and State law, and the implementation of that law, whether statutory or otherwise, and whether adopted before or after [RFRA's enactment]." In accordance with RFRA's usage of the term, we shall use "state law" to include local and municipal ordinances.

IV. Coca Cases Pre-Monopoly

Mellouli v. Lynch 575 U.S. ____ (2015)

Pre-1970 Coca Statutes applied with the Controlled Substances Act

Linder v. United States 268 U.S. 5 (1925)

"The Harrison Narcotic Law, approved December 17, 1914, c. 1, 38 Stat. 785 -- 12 sections -- is entitled:

"An Act to provide for the registration of, with collectors of internal revenue, and to impose a special tax upon all persons who produce, import, manufacture, compound, deal in, dispense, sell, distribute, or give away opium or coca leaves, their salts, derivatives, or preparations, and for other purposes."

Section 1 provides:

"That on and after the first day of March, nineteen hundred and fifteen, every person [with exceptions not here important] who produces, imports, manufactures, compounds, deals in, dispenses, sells, distributes, or gives away opium or coca leaves or any compound, manufacture, salt, derivative, or preparation thereof, shall register with the collector of internal revenue,"

...

The declared object of the Narcotic Law is to provide revenue, and this Court has held that whatever additional moral end it may have in view must "be reached only through a revenue measure and within the limits of a revenue measure." United States v. Jin Fuey Moy, [241 U. S. 394](#), [241 U. S. 402](#). Congress cannot, under the pretext of executing delegated power, pass laws for the accomplishment of objects not intrusted to the federal government. And we accept as established doctrine that any provision of an Act of Congress ostensibly enacted under power granted by the Constitution, not naturally and reasonably adapted to the effective exercise of such power, but solely to the achievement of something plainly within power

reserved to the states, is invalid and cannot be enforced. [McCulloch v. Maryland](#), 4 Wheat, 316, 17 U. S. 423; [License Tax Cases](#), 5 Wall. 462; [United States v. De Witt](#), 9 Wall. 41; Keller v. United States, 213 U. S. 138; Hammer v. Dagenhart, 247 U. S. 251; Child Labor Tax Case, 259 U. S. 20. In the light of these principles, and not forgetting the familiar rule that "a statute must be construed, if fairly possible, so as to avoid, not only the conclusion that it is unconstitutional, but also grave doubts upon that score,"

...

Obviously, direct control of medical practice in the states is beyond the power of the federal government. Incidental regulation of such practice by Congress through a taxing act cannot extend to matters plainly inappropriate and unnecessary to reasonable enforcement of a revenue measure. The enactment under consideration levies a tax, upheld by this Court, upon every person who imports, manufactures, produces, compounds, sells, deals in, dispenses or gives away opium or coca leaves or derivatives therefrom, and may regulate medical practice in the states only so far as reasonably appropriate for or merely incidental to its enforcement. It says nothing of "addicts," and does not undertake to prescribe methods for their medical treatment. They are diseased, and proper subjects for such treatment, and we cannot possibly conclude that a physician acted improperly or unwisely or for other than medical purposes solely because he has dispensed to one of them, in the ordinary course and in good faith, four small tablets of morphine or cocaine for relief of conditions incident to addiction. What constitutes bona fide medical practice must be determined upon consideration of evidence and attending circumstances. Mere pretense of such practice, of course, cannot legalize forbidden sales, or otherwise nullify valid provisions of the statute, or defeat such regulations as may be fairly appropriate to its enforcement within the proper limitations of a revenue measure. *United States v. Jin Fuey Moy*, *supra*, points out that the Narcotic Law can be upheld only as a revenue measure. It must be interpreted and applied accordingly. Further, grave constitutional doubts concerning § 8 cannot be avoided unless limited to persons who are required to register by § 1. Mere possession of the drug creates no presumption of guilt as against any other person.

In *United States v. Doremus*, 249 U. S. 86, 249 U. S. 93, 249 U. S. 95, a registered physician was accused of unlawfully selling, giving away and distributing 500 one-sixth grain tablets of heroin without official written order. Another count charged selling, dispensing and distributing 500 such tablets not in the course of regular professional practice. The trial court held § 2 invalid because it invaded the police power of the state. This Court declared: "Of course, Congress may not, in the exercise of federal power, exert authority wholly reserved to the states. . . ."

V. Marijuana Cases Pre-Monopoly

Possession of marihuana is a crime in Texas, where petitioner was arrested, in New York, where petitioner asserted the transfer occurred, and in all the other States. Section 4744(a)(2)

prohibits transportation or concealment of marihuana by one who acquired it without having paid the transfer tax, which petitioner conceded that he had not done. Petitioner claimed in his motion for a new trial that his conviction under the Marihuana Tax Act violated his privilege against self-incrimination, and he argues that this Court's subsequent decisions in *Marchetti v. United States*, [390 U. S. 39](#), *Grosso v. United States*, [390 U. S. 62](#), and *Haynes v. United States*, [390 U. S. 85](#), require reversal. The Government contends that the Act's transfer tax provisions do not compel incriminatory disclosures because, as administratively construed and applied, they permit prepayment of the tax only by persons whose activities are otherwise lawful. Title 21 U.S.C. § 176a makes it a crime to transport or facilitate the transportation of illegally imported marihuana, with knowledge of its illegal importation, and provides that a defendant's possession of marihuana shall be deemed sufficient evidence that the marihuana was illegally imported or brought into the United States, and that the defendant knew of the illegal importation or bringing in, unless the defendant explains his possession to the satisfaction of the jury. The trial court instructed the jury that it might find petitioner guilty of violating § 176a (1) solely on petitioner's testimony that the marihuana had been brought back from Mexico into the United States and that, with knowledge of that fact, petitioner had continued to transport it, or (2) partly upon his testimony that he had transported the marihuana from New York to Texas and partly upon the § 176a presumption. Petitioner contends that application of that presumption denied him due process of law. Petitioner's invocation of the privilege against self-incrimination under the Fifth Amendment provided a full defense to the charge under 26 U.S.C. § 4744(a)(2). Pp. [395 U. S. 12](#)-29.

We consider first petitioner's claim that his conviction under the Marihuana Tax Act violated his privilege against self-incrimination. Petitioner argues that reversal of his Marihuana Tax Act conviction is required by our decisions of last Term in *Marchetti v. United States*, [390 U. S. 39](#) (1968), *Grosso v. United States*, [390 U. S. 62](#) (1968), and *Haynes v. United States*, [390 U. S. 85](#) (1968). In *Marchetti*, we held that a plea of the Fifth Amendment privilege provided a complete defense to a prosecution for failure to register and pay the occupational tax on wagers, as required by 26 U.S.C. §§ 4411-4412. We noted that wagering was a crime in almost every State, and that 26 U.S.C. § 6107 required that lists of wagering taxpayers be furnished to state and local prosecutors on demand. We concluded that compliance with the statute would have subjected petitioner to a "*real and appreciable*" risk of self-incrimination. We further recognized that the occupational tax was not imposed in "an essentially noncriminal and regulatory area . . . ," [390 U.S. at 390 U. S. 57](#), but was "directed to a `selective group inherently suspect of criminal activities.'" We found that it would be inappropriate to impose restrictions on use of the information collected under the statute -- a course urged by the Government as a means of removing the impact of the statute upon the privilege against self-incrimination -- because of the evident congressional purpose to provide aid to prosecutors. We noted that, unlike the petitioner in *Shapiro v. United States*, [335 U. S. 1](#) (1948), *Marchetti* was not required to supply information which had a "public aspect" or was contained in records of the kind he customarily kept.

In *Grosso*, we held that the same considerations required that a claim of the privilege be a defense to prosecution under 26 U.S.C. § 4401, which imposes an excise tax on proceeds from

wagering. And in *Haynes*, we held for the same reasons that assertion of the Fifth Amendment privilege provided a defense to prosecution for possession of an unregistered weapon under the National Firearms Act, 26 U.S.C. § 5851, despite the fact that, in "uncommon" instances, registration under the statute would not be incriminating. See 390 U.S. at [390 U. S. 96-97](#), [390 U. S. 99](#). In order to understand petitioner's contention that compliance with the Marihuana Tax Act would have obliged him to incriminate himself within the meaning of the foregoing decisions, it is necessary to be familiar with the statutory scheme. The Marihuana Tax Act has two main subparts. The first imposes a tax on transfers of marihuana, the second an occupational tax upon those who deal in the drug. It is convenient to begin with the occupational tax provisions, 26 U.S.C. §§ 4751-4753.

Section 4751 provides that all persons who "deal in" marihuana shall be subject to an annual occupational tax. Subsections require that specified categories of persons, such as importers, producers, physicians, researchers, and millers pay varying rates of tax per year. See §§ 4751(1)-(4), (6). Persons who "deal in" marihuana but do not fall into any of the specified categories are required to pay \$3 per year. See § 4751(5). Section 4753 provides that, at the time of paying the tax, the taxpayer must "register his name or style and his place or places of business" at the nearest district office of the Internal Revenue Service.

The first of the transfer tax provisions, 26 U.S.C. § 4741, imposes a tax "upon all transfers of marihuana which are required by section 4742 to be carried out in pursuance of written order forms." Section 4741 further provides that, on transfers to persons registered under § 4753, the tax is \$1 per ounce, while, on transfers to persons not so registered, the tax is \$100 per ounce. The tax is required to be paid by the transferee "at the time of securing each order form." With certain exceptions not here relevant, § 4742 makes it unlawful for any person, "whether or not required to pay a special tax and register under sections 4751 to 4753," to transfer marihuana except pursuant to a written order form to be obtained by the transferee. A regulation, 26 CFR § 152.69, provides that the order form must show the name and address of the transferor and transferee, their § 4753 registration numbers, if they are registered, and the quantity of marihuana transferred. Another regulation, 26 CFR § 152.66, requires the transferee to submit an application containing these data in order to obtain the form. Section 4742(d) of the Act requires the Internal Revenue Service to "preserve" in its records a duplicate copy of each order form which it issues.

Another statutory provision, 26 U.S.C. § 4773, assures that the information contained in the order form will be available to law enforcement officials. That section provides that the duplicate order forms required to be kept by the Internal Revenue Service shall be open to inspection by Treasury personnel and state and local officials charged with enforcement of marihuana laws, and that, upon payment of a fee, such officials shall be furnished copies of the forms.

Finally, 26 U.S.C. § 4744(a) makes it unlawful for a transferee required to pay the § 4741(a) transfer tax either to acquire marihuana without having paid the tax or to transport, conceal, or facilitate the transportation or concealment of, any marihuana so acquired. Petitioner was convicted under § 4744(a). He conceded at trial that he had not obtained an order form or paid the transfer tax.

If read according to its terms, the Marihuana Tax Act compelled petitioner to expose himself to a "real and appreciable" risk of self-incrimination within the meaning of our decisions in *Marchetti*, *Grosso*, and *Haynes*. Sections 4741-4742 required him, in the course of obtaining an order form, to identify himself not only as a transferee of marihuana, but as a transferee who had not registered and paid the occupational tax under §§ 4751-4753. Section 4773 directed that this information be conveyed by the Internal Revenue Service to state and local law enforcement officials on request.

Petitioner had ample reason to fear that transmittal to such officials of the fact that he was a recent, unregistered transferee of marihuana "would surely prove a significant *link in a chain*' of evidence tending to establish his guilt" under the state marihuana laws then in effect. When petitioner failed to comply with the Act, in late 1965, possession of any quantity of marihuana was apparently a crime in every one of the 50 States, including New York, where petitioner claimed the transfer occurred, and Texas, where he was arrested and convicted. It is true that almost all States, including New York and Texas, had exceptions making lawful, under specified conditions, possession of marihuana by: (1) state-licensed manufacturers and wholesalers; (2) apothecaries; (3) researchers; (4) physicians, dentists, veterinarians, and certain other medical personnel; (5) agents or employees of the foregoing persons or common carriers; (6) persons for whom the drug had been prescribed or to whom it had been given by an authorized medical person, and (7) certain public officials. However, individuals in the first four of these classes are among those compelled to register and pay the occupational tax under §§ 4751-4753; in consequence of having registered, they are required to pay only a \$1 per ounce transfer tax under § 4741(a)(1). It is extremely unlikely that such persons will remain unregistered, for failure to register renders them liable not only to an additional \$99 per ounce transfer tax, but also to severe criminal penalties. Persons in the last three classes mentioned above appear to be wholly exempt from the order form and transfer tax requirements.

Thus, at the time petitioner failed to comply with the Act, those persons who might legally possess marihuana under state law were virtually certain either to be registered under § 4753 or to be exempt from the order form requirement. It follows that the class of possessors who were both unregistered and obliged to obtain an order form constituted a "selective group inherently suspect of criminal activities." Since compliance with the transfer tax provisions would have required petitioner unmistakably to identify himself as a member of this "selective" and "suspect" group, we can only decide that, when read according to their terms, these provisions created a "real and appreciable" hazard of incrimination.

VI. Coca in USC based on CSA

Not being applied properly

21 U.S. Code § 952

“(a) Controlled substances in schedule I or II and narcotic drugs in schedule III, IV, or V; exceptions

It shall be unlawful to import into the customs territory of the United States from any place outside thereof (but within the United States), or to import into the United States from any place outside thereof, any controlled substance in schedule I or II of subchapter I, or any narcotic drug in schedule III, IV, or V of subchapter I, or ephedrine, pseudoephedrine, or phenylpropanolamine, except that—

(1)

such amounts of crude opium, poppy straw, concentrate of poppy straw, and coca leaves, and of ephedrine, pseudoephedrine, and phenylpropanolamine, as the Attorney General finds to be necessary to provide for medical, scientific, or other legitimate purposes, and

(2) such amounts of any controlled substance in schedule I or II or any narcotic drug in schedule III, IV, or V that the Attorney General finds to be necessary to provide for the medical, scientific, or other legitimate needs of the United States—

(A)

during an emergency in which domestic supplies of such substance or drug are found by the Attorney General to be inadequate,

(B)

in any case in which the Attorney General finds that competition among domestic manufacturers of the controlled substance is inadequate and will not be rendered adequate by the registration of additional manufacturers under [section 823 of this title](#),

or

(C)

in any case in which the Attorney General finds that such controlled substance is in limited quantities exclusively for scientific, analytical, or research uses, may be so imported under such regulations as the Attorney General shall prescribe. No crude opium may be so imported for the purpose of manufacturing heroin or smoking opium.

(b) Nonnarcotic controlled substances in schedule III, IV, or V It shall be unlawful to import into the customs territory of the United States from any place outside thereof (but within the United States), or to import into the United States from any place outside thereof, any nonnarcotic controlled substance in schedule III, IV, or V, unless such nonnarcotic controlled substance—

(1)

is imported for medical, scientific, or other legitimate uses, and

(2)

is imported pursuant to such notification, or declaration, or in the case of any nonnarcotic controlled substance in schedule III, such import permit, notification, or declaration, as the Attorney General may by regulation prescribe, except that if a nonnarcotic controlled substance in schedule IV or V is also listed in schedule I or II of the Convention on Psychotropic Substances it shall be imported pursuant to such import permit requirements, prescribed by regulation of the Attorney General, as are required by the Convention.

(c) Coca leaves

In addition to the amount of coca leaves authorized to be imported into the United States under subsection (a), the Attorney General may permit the importation of additional amounts of coca leaves. All cocaine and ecgonine (and all salts, derivatives, and preparations from which cocaine or ecgonine may be synthesized or made) contained in such additional amounts of coca leaves imported under this subsection shall be destroyed under the supervision of an authorized representative of the Attorney General.

Title 21 §1304.32 Reports of manufacturers importing coca leaves.

(a) Every manufacturer importing or manufacturing from raw coca leaves shall submit information accounting for the importation and for all manufacturing operations performed between the importation and the manufacture of bulk or finished products standardized in accordance with U.S. Pharmacopoeia, National Formulary, or other recognized standards. The reports shall be submitted quarterly on company letterhead to the Drug and Chemical Evaluation Section, Drug Enforcement Administration, on or before the 15th day of the month immediately following the period for which it is submitted. See the Table of DEA Mailing Addresses in [Sec. 1321.01](#) of this chapter for the current mailing address.

(b) The following information shall be submitted for raw coca leaf, ecgonine, ecgonine for conversion or further manufacture, benzoylecgonine, manufacturing coca extracts (list for tinctures and extracts; and others separately), other crude alkaloids and other derivatives (quantities should be reported as grams of actual quantity involved and the cocaine alkaloid content or equivalency):

(1) Beginning inventory;

(2) Imports;

(3) Gains on reweighing;

(4) Quantity purchased;

- (5) *Quantity produced;*
 - (6) *Other receipts;*
 - (7) *Quantity returned to processes for reworking;*
 - (8) *Material used in purification for sale;*
 - (9) *Material used for manufacture or production;*
 - (10) *Losses on reweighing;*
 - (11) *Material used for conversion;*
 - (12) *Other dispositions and*
 - (13) *Ending inventory.*
- (c) *The following information shall be submitted for importation of coca leaves:*
 - (1) *Import permit number;*
 - (2) *Date the shipment arrived at the United States port of entry;*
 - (3) *Actual quantity shipped;*
 - (4) *Assay (percent) of cocaine alkaloid and*
 - (5) *Total cocaine alkaloid content.*
- (d) *Upon importation of coca leaves, samples will be selected and assays made by the importing manufacturer in accordance with recognized chemical procedures. These assays shall form the basis of accounting for such coca leaves, which shall be accounted for in terms of their cocaine alkaloid content or equivalency or their total anhydrous coca alkaloid content. Where final assay data is not determined at the time of submission, the report shall be made on the basis of the best data available, subject to adjustment, and the necessary adjusting entries shall be made on the next report.*
- (e) *Where factory procedure is such that partial withdrawals of medicinal coca leaves are made from individual containers, there shall be attached to the container a stock record card on which shall be kept a complete record of withdrawals therefrom.*
- (f) *All in-process inventories should be expressed in terms of end-products and not precursors. Once precursor material has been changed or placed into process for the manufacture of a specified end-product, it must no longer be accounted for as precursor stocks available for conversion or use, but rather as end-product in-process inventories.*

VII. Texas Religious Code

TITLE 5. GOVERNMENTAL LIABILITY CHAPTER 110. RELIGIOUS FREEDOM

Sec. 110.001. DEFINITIONS. (a) In this chapter:

- (1) "Free exercise of religion" means an act or refusal to act that is substantially motivated by sincere religious belief. In determining whether an act or

refusal to act is substantially motivated by sincere religious belief under this chapter, it is not necessary to determine that the act or refusal to act is motivated by a central part or central requirement of the person's sincere religious belief.

(2) "Government agency" means:

(A) this state or a municipality or other political subdivision of this state; and

(B) any agency of this state or a municipality or other political subdivision of this state, including a department, bureau, board, commission, office, agency, council, or public institution of higher education.

(b) In determining whether an interest is a compelling governmental interest under Section [110.003](#), a court shall give weight to the interpretation of compelling interest in federal case law relating to the free exercise of religion clause of the First Amendment of the United States Constitution.

Sec. 110.002. APPLICATION. (a) This chapter applies to any ordinance, rule, order, decision, practice, or other exercise of governmental authority.

(b) This chapter applies to an act of a government agency, in the exercise of governmental authority, granting or refusing to grant a government benefit to an individual.

(c) This chapter applies to each law of this state unless the law is expressly made exempt from the application of this chapter by reference to this chapter.

Sec. 110.008. SOVEREIGN IMMUNITY WAIVED. (a) Subject to Section [110.006](#), sovereign immunity to suit and from liability is waived and abolished to the extent of liability created by Section [110.005](#), and a claimant may sue a government agency for damages allowed by that section.

(b) Notwithstanding Subsection (a), this chapter does not waive or abolish sovereign immunity to suit and from liability under the Eleventh Amendment to the United States Constitution.

VIII. US Code

42 U.S. Code § 2000bb - Congressional findings and declaration of purposes

(a) FindingsThe Congress finds that—

(1)

the framers of the Constitution, recognizing free exercise of religion as an unalienable right, secured its protection in the First Amendment to the Constitution;

(2)

laws “neutral” toward religion may burden religious exercise as surely as laws intended to interfere with religious exercise;

(3)

governments should not substantially burden religious exercise without compelling justification;

(4)

in *Employment Division v. Smith*, [494 U.S. 872 \(1990\)](#) the Supreme Court virtually eliminated the requirement that the government justify burdens on religious exercise imposed by laws neutral toward religion; and

(5)

the compelling interest test as set forth in prior Federal court rulings is a workable test for striking sensible balances between religious liberty and competing prior governmental interests.

(b) Purposes The purposes of this chapter are—

(1)

to restore the compelling interest test as set forth in *Sherbert v. Verner*, [374 U.S. 398 \(1963\)](#) and *Wisconsin v. Yoder*, [406 U.S. 205 \(1972\)](#) and to guarantee its application in all cases where free exercise of religion is substantially burdened; and

(2)

to provide a claim or defense to persons whose religious exercise is substantially burdened by government.

42 U.S. Code § 2000bb–1 - Free exercise of religion protected

(a) In general

Government shall not substantially burden a person’s exercise of religion even if the burden results from a rule of general applicability, except as provided in subsection (b) of this section.

(b) Exception Government may substantially burden a person’s exercise of religion only if it demonstrates that application of the burden to the person—

(1)

is in furtherance of a compelling governmental interest; and

(2)

is the least restrictive means of furthering that compelling governmental interest.

(c) Judicial relief

A person whose religious exercise has been burdened in violation of this section may assert that violation as a claim or defense in a judicial proceeding and obtain appropriate relief against a government. Standing to assert a claim or defense under

this section shall be governed by the general rules of standing under article III of the Constitution.

42 U.S. Code § 2000bb–2 - Definitions

As used in this chapter—

(1)

the term “government” includes a branch, department, agency, instrumentality, and official (or other person acting under color of law) of the United States, or of a covered entity;

(2)

the term “covered entity” means the District of Columbia, the Commonwealth of Puerto Rico, and each territory and possession of the United States;

(3)

the term “demonstrates” means meets the burdens of going forward with the evidence and of persuasion; and

(4)

the term “exercise of religion” means religious exercise, as defined in [section 2000cc–5 of this title](#).

42 U.S. Code § 2000bb–3 - Applicability

(a) In general

This chapter applies to all Federal law, and the implementation of that law, whether statutory or otherwise, and whether adopted before or after November 16, 1993.

(b) Rule of construction

Federal statutory law adopted after November 16, 1993, is subject to this chapter unless such law explicitly excludes such application by reference to this chapter.

(c) Religious belief unaffected

Nothing in this chapter shall be construed to authorize any government to burden any religious belief.

42 U.S. Code § 2000cc–3 - Rules of construction

(a) Religious belief unaffected

Nothing in this chapter shall be construed to authorize any government to burden any religious belief.

(b) Religious exercise not regulated

Nothing in this chapter shall create any basis for restricting or burdening religious exercise or for claims against a religious organization including any religiously affiliated school or university, not acting under color of law.

(c) Claims to funding unaffected

Nothing in this chapter shall create or preclude a right of any religious organization to receive funding or other assistance from a government, or of any person to receive government funding for a religious activity, but this chapter may require a government to incur expenses in its own operations to avoid imposing a substantial burden on religious exercise.

(d) Other authority to impose conditions on funding unaffected Nothing in this chapter shall—

(1)

authorize a government to regulate or affect, directly or indirectly, the activities or policies of a person other than a government as a condition of receiving funding or other assistance; or

(2)

restrict any authority that may exist under other law to so regulate or affect, except as provided in this chapter.

(e) Governmental discretion in alleviating burdens on religious exercise

A government may avoid the preemptive force of any provision of this chapter by changing the policy or practice that results in a substantial burden on religious exercise, by retaining the policy or practice and exempting the substantially burdened religious exercise, by providing exemptions from the policy or practice for applications that substantially burden religious exercise, or by any other means that eliminates the substantial burden.

(f) Effect on other law

With respect to a claim brought under this chapter, proof that a substantial burden on a person's religious exercise affects, or removal of that burden would affect, commerce with foreign nations, among the several States, or with Indian tribes, shall not establish any inference or presumption that Congress intends that any religious exercise is, or is not, subject to any law other than this chapter.

(g) Broad construction

This chapter shall be construed in favor of a broad protection of religious exercise, to the maximum extent permitted by the terms of this chapter and the Constitution.

(h) No preemption or repeal

Nothing in this chapter shall be construed to preempt State law, or repeal Federal law, that is equally as protective of religious exercise as, or more protective of religious exercise than, this chapter.

(i) Severability

If any provision of this chapter or of an amendment made by this chapter, or any application of such provision to any person or circumstance, is held to be unconstitutional, the remainder of this chapter, the amendments made by this chapter, and the application of the provision to any other person or circumstance shall not be affected.

42 U.S. Code § 2000cc–2 - Judicial relief

a) Cause of action

A person may assert a violation of this chapter as a claim or defense in a judicial proceeding and obtain appropriate relief against a government. Standing to assert a claim or defense under this section shall be governed by the general rules of standing under article III of the Constitution.

(b) Burden of persuasion

If a plaintiff produces prima facie evidence to support a claim alleging a violation of the Free Exercise Clause or a violation of [section 2000cc of this title](#), the government shall bear the burden of persuasion on any element of the claim, except that the plaintiff shall bear the burden of persuasion on whether the law (including a regulation) or government practice that is challenged by the claim substantially burdens the plaintiff's exercise of religion.

(c) Full faith and credit

Adjudication of a claim of a violation of [section 2000cc of this title](#) in a non-Federal forum shall not be entitled to full faith and credit in a Federal court unless the claimant had a full and fair adjudication of that claim in the non-Federal forum.

(d) Omitted

(e) Prisoners

Nothing in this chapter shall be construed to amend or repeal the Prison Litigation Reform Act of 1995 (including provisions of law amended by that Act).

(f) Authority of United States to enforce this chapter

The United States may bring an action for injunctive or declaratory relief to enforce compliance with this chapter. Nothing in this subsection shall be construed to deny, impair, or otherwise affect any right or authority of the Attorney General, the United States, or any agency, officer, or employee of the United States, acting under any law other than this subsection, to institute or intervene in any proceeding.

(g) Limitation

If the only jurisdictional basis for applying a provision of this chapter is a claim that a substantial burden by a government on religious exercise affects, or that removal of that substantial burden would affect, commerce with foreign nations, among the several States, or with Indian tribes, the provision shall not apply if the government

demonstrates that all substantial burdens on, or the removal of all substantial burdens from, similar religious exercise throughout the Nation would not lead in the aggregate to a substantial effect on commerce with foreign nations, among the several States, or with Indian tribes.

42 U.S. Code § 2000cc–5 - Definitions

In this chapter:

(1) Claimant

The term “claimant” means a person raising a claim or defense under this chapter.

(2) Demonstrates

The term “demonstrates” means meets the burdens of going forward with the evidence and of persuasion.

(3) Free Exercise Clause

The term “Free Exercise Clause” means that portion of the first amendment to the Constitution that proscribes laws prohibiting the free exercise of religion.

(4) GovernmentThe term “government”—

(A) means—

(i)

a State, county, municipality, or other governmental entity created under the authority of a State;

(ii)

any branch, department, agency, instrumentality, or official of an entity listed in clause

(i); and

(iii)

any other person acting under color of State law; and

(B)

for the purposes of sections 2000cc–2(b) and 2000cc–3 of this title, includes the United States, a branch, department, agency, instrumentality, or official of the United States, and any other person acting under color of Federal law.

(5) Land use regulation

The term “land use regulation” means a zoning or landmarking law, or the application of such a law, that limits or restricts a claimant’s use or development of land (including a structure affixed to land), if the claimant has an ownership, leasehold, easement, servitude, or other property interest in the regulated land or a contract or option to acquire such an interest.

(6) Program or activity

The term “program or activity” means all of the operations of any entity as described in paragraph (1) or (2) of [section 2000d–4a of this title](#).

(7) Religious exercise

(A) In general

The term “religious exercise” includes any exercise of religion, whether or not compelled by, or central to, a system of religious belief.

(B) Rule

The use, building, or conversion of real property for the purpose of religious exercise shall be considered to be religious exercise of the person or entity that uses or intends to use the property for that purpose.

IX. Texas State Constitution & Code

ARTICLE 1. BILL OF RIGHTS

Sec. 3. EQUAL RIGHTS. All free men, when they form a social compact, have equal rights, and no man, or set of men, is entitled to exclusive separate public emoluments, or privileges, but in consideration of public services.

Sec. 3a. EQUALITY UNDER THE LAW. Equality under the law shall not be denied or abridged because of sex, race, color, creed, or national origin. This amendment is self-operative.

Sec. 4. RELIGIOUS TESTS. No religious test shall ever be required as a qualification to any office, or public trust, in this State; nor shall any one be excluded from holding office on account of his religious sentiments, provided he acknowledge the existence of a Supreme Being.

Sec. 5. WITNESSES NOT DISQUALIFIED BY RELIGIOUS BELIEFS; OATHS AND AFFIRMATIONS. No person shall be disqualified to give evidence in any of the Courts of this State on account of his religious opinions, or for the want of any religious belief, but all oaths or affirmations shall be administered in the mode most binding upon the conscience, and shall be taken subject to the pains and penalties of perjury.

Sec. 6. FREEDOM OF WORSHIP. All men have a natural and indefeasible right to worship Almighty God according to the dictates of their own consciences. No man shall be compelled to attend, erect or support any place of worship, or to maintain any ministry against his consent. No human authority ought, in any case whatever, to control or interfere with the rights of conscience in matters of religion, and no preference shall ever be given by law to any religious society or mode of worship. But it shall be the duty of the Legislature to pass such laws as may be necessary to protect equally every religious denomination in the peaceable enjoyment of its own mode of public worship.

Sec. 9. SEARCHES AND SEIZURES. The people shall be secure in their persons, houses, papers and possessions, from all unreasonable seizures or searches, and no warrant to search any place, or to seize any person or thing, shall issue without

describing them as near as may be, nor without probable cause, supported by oath or affirmation.

HEALTH AND SAFETY CODE
TITLE 6. FOOD, DRUGS, ALCOHOL, AND HAZARDOUS SUBSTANCES
SUBTITLE C. SUBSTANCE ABUSE REGULATION AND CRIMES
CHAPTER 481. TEXAS CONTROLLED SUBSTANCES ACT
SUBCHAPTER A. GENERAL PROVISIONS

Sec. 481.111. EXEMPTIONS. (a) The provisions of this chapter relating to the possession and distribution of peyote do not apply to the use of peyote by a member of the Native American Church in bona fide religious ceremonies of the church. However, a person who supplies the substance to the church must register and maintain appropriate records of receipts and disbursements in accordance with rules adopted by the director. An exemption granted to a member of the Native American Church under this section does not apply to a member with less than 25 percent Indian blood.

(b) The provisions of this chapter relating to the possession of denatured sodium pentobarbital do not apply to possession by personnel of a humane society or an animal control agency for the purpose of destroying injured, sick, homeless, or unwanted animals if the humane society or animal control agency is registered with the Federal Drug Enforcement Administration. The provisions of this chapter relating to the distribution of denatured sodium pentobarbital do not apply to a person registered as required by Subchapter C, who is distributing the substance for that purpose to a humane society or an animal control agency registered with the Federal Drug Enforcement Administration.

(c) A person does not violate Section [481.113](#), [481.116](#), [481.1161](#), [481.121](#), or [481.125](#) if the person possesses or delivers tetrahydrocannabinols or their derivatives, or drug paraphernalia to be used to introduce tetrahydrocannabinols or their derivatives into the human body, for use in a federally approved therapeutic research program.

(d) The provisions of this chapter relating to the possession and distribution of anabolic steroids do not apply to the use of anabolic steroids that are administered to livestock or poultry.

(e) Sections [481.120](#), [481.121](#), [481.122](#), and [481.125](#) do not apply to a person who engages in the acquisition, possession, production, cultivation, delivery, or disposal of a raw material used in or by-product created by the production or cultivation of low-THC cannabis if the person:

(1) for an offense involving possession only of marihuana or drug paraphernalia, is a patient for whom low-THC cannabis is prescribed under Chapter [169](#), Occupations Code, or the patient's legal guardian, and the person possesses

low-THC cannabis obtained under a valid prescription from a dispensing organization;
or

(2) is a director, manager, or employee of a dispensing organization and the person, solely in performing the person's regular duties at the organization, acquires, possesses, produces, cultivates, dispenses, or disposes of:

(A) in reasonable quantities, any low-THC cannabis or raw materials used in or by-products created by the production or cultivation of low-THC cannabis; or

(B) any drug paraphernalia used in the acquisition, possession, production, cultivation, delivery, or disposal of low-THC cannabis.

(f) For purposes of Subsection (e):

(1) "Dispensing organization" has the meaning assigned by Section [487.001](#).

(2) "Low-THC cannabis" has the meaning assigned by Section [169.001](#), Occupations Code.

HEALTH AND SAFETY CODE

TITLE 6. FOOD, DRUGS, ALCOHOL, AND HAZARDOUS SUBSTANCES

SUBTITLE C. SUBSTANCE ABUSE REGULATION AND CRIMES

CHAPTER 487. TEXAS COMPASSIONATE-USE ACT

SUBCHAPTER A. GENERAL PROVISIONS

Sec. 487.001. DEFINITIONS. In this chapter:

(1) "Department" means the Department of Public Safety.

(2) "Director" means the public safety director of the department.

(3) "Dispensing organization" means an organization licensed by the department to cultivate, process, and dispense low-THC cannabis to a patient for whom low-THC cannabis is prescribed under Chapter [169](#), Occupations Code.

(4) "Low-THC cannabis" has the meaning assigned by Section [169.001](#), Occupations Code.

Added by Acts 2015, 84th Leg., R.S., Ch. 301 (S.B. [339](#)), Sec. 1, eff. June 1, 2015.

SUBCHAPTER B. DUTIES OF DEPARTMENT

Sec. 487.051. DUTIES OF DEPARTMENT. The department shall administer this chapter.

Added by Acts 2015, 84th Leg., R.S., Ch. 301 (S.B. [339](#)), Sec. 1, eff. June 1, 2015.

Sec. 487.052. RULES. The director shall adopt any rules necessary for the administration and enforcement of this chapter, including rules imposing fees under this chapter in amounts sufficient to cover the cost of administering this chapter.

Added by Acts 2015, 84th Leg., R.S., Ch. 301 (S.B. [339](#)), Sec. 1, eff. June 1, 2015.

Sec. 487.053. LICENSING OF DISPENSING ORGANIZATIONS AND REGISTRATION OF CERTAIN ASSOCIATED INDIVIDUALS. (a) The department shall:

- (1) issue or renew a license to operate as a dispensing organization to each applicant who satisfies the requirements established under this chapter; and
- (2) register directors, managers, and employees of each dispensing organization.

(b) The department shall enforce compliance of licensees and registrants and shall adopt procedures for suspending or revoking a license or registration issued under this chapter and for renewing a license or registration issued under this chapter.

Added by Acts 2015, 84th Leg., R.S., Ch. 301 (S.B. [339](#)), Sec. 1, eff. June 1, 2015.

Sec. 487.054. COMPASSIONATE-USE REGISTRY. (a) The department shall establish and maintain a secure online compassionate-use registry that contains:

- (1) the name of each physician who registers as the prescriber for a patient under Section [169.004](#), Occupations Code, the name and date of birth of the patient, the dosage prescribed, the means of administration ordered, and the total amount of low-THC cannabis required to fill the patient's prescription; and
- (2) a record of each amount of low-THC cannabis dispensed by a dispensing organization to a patient under a prescription.

(b) The department shall ensure the registry:

- (1) is designed to prevent more than one qualified physician from registering as the prescriber for a single patient;
- (2) is accessible to law enforcement agencies and dispensing organizations for the purpose of verifying whether a patient is one for whom low-THC cannabis is prescribed and whether the patient's prescriptions have been filled; and
- (3) allows a physician qualified to prescribe low-THC cannabis under Section [169.002](#), Occupations Code, to input safety and efficacy data derived from the

treatment of patients for whom low-THC cannabis is prescribed under Chapter [169](#),
Occupations Code.

Added by Acts 2015, 84th Leg., R.S., Ch. 301 (S.B. [339](#)), Sec. 1, eff. June 1, 2015.

SUBCHAPTER C. LICENSE TO OPERATE AS DISPENSING ORGANIZATION

Sec. 487.101. LICENSE REQUIRED. A license issued by the department under this chapter is required to operate a dispensing organization.

Added by Acts 2015, 84th Leg., R.S., Ch. 301 (S.B. [339](#)), Sec. 1, eff. June 1, 2015.

Sec. 487.102. ELIGIBILITY FOR LICENSE. An applicant for a license to operate as a dispensing organization is eligible for the license if:

- (1) as determined by the department, the applicant possesses:
 - (A) the technical and technological ability to cultivate and produce low-THC cannabis;
 - (B) the ability to secure:
 - (i) the resources and personnel necessary to operate as a dispensing organization; and
 - (ii) premises reasonably located to allow patients listed on the compassionate-use registry access to the organization through existing infrastructure;
 - (C) the ability to maintain accountability for the raw materials, the finished product, and any by-products used or produced in the cultivation or production of low-THC cannabis to prevent unlawful access to or unlawful diversion or possession of those materials, products, or by-products; and
 - (D) the financial ability to maintain operations for not less than two years from the date of application;
- (2) each director, manager, or employee of the applicant is registered under Subchapter D; and
- (3) the applicant satisfies any additional criteria determined by the director to be necessary to safely implement this chapter.

Added by Acts 2015, 84th Leg., R.S., Ch. 301 (S.B. [339](#)), Sec. 1, eff. June 1, 2015.

Sec. 487.103. APPLICATION. (a) A person may apply for an initial or renewal license to operate as a dispensing organization by submitting a form prescribed by the department along with the application fee in an amount set by the director.

(b) The application must include the name and address of the applicant, the name and address of each of the applicant's directors, managers, and employees, and any other information considered necessary by the department to determine the applicant's eligibility for the license.

Added by Acts 2015, 84th Leg., R.S., Ch. 301 (S.B. [339](#)), Sec. 1, eff. June 1, 2015.

Sec. 487.104. ISSUANCE, RENEWAL, OR DENIAL OF LICENSE. (a) The department shall issue or renew a license to operate as a dispensing organization only if:

(1) the department determines the applicant meets the eligibility requirements described by Section [487.102](#); and

(2) issuance or renewal of the license is necessary to ensure reasonable statewide access to, and the availability of, low-THC cannabis for patients registered in the compassionate-use registry and for whom low-THC cannabis is prescribed under Chapter [169](#), Occupations Code.

(b) If the department denies the issuance or renewal of a license under Subsection (a), the applicant is entitled to a hearing. The department shall give written notice of the grounds for denial to the applicant at least 30 days before the date of the hearing.

(c) A license issued or renewed under this section expires on the second anniversary of the date of issuance or renewal, as applicable.

Added by Acts 2015, 84th Leg., R.S., Ch. 301 (S.B. [339](#)), Sec. 1, eff. June 1, 2015.

Sec. 487.105. CRIMINAL HISTORY BACKGROUND CHECK. (a) An applicant for the issuance or renewal of a license to operate as a dispensing organization shall provide the department with the applicant's name and the name of each of the applicant's directors, managers, and employees.

(b) Before a dispensing organization licensee hires a manager or employee for the organization, the licensee must provide the department with the name of the prospective manager or employee. The licensee may not transfer the license to another person before that prospective applicant and the applicant's directors, managers, and

employees pass a criminal history background check and are registered as required by Subchapter D.

(c) The department shall conduct a criminal history background check on each individual whose name is provided to the department under Subsection (a) or (b). The director by rule shall:

(1) determine the manner by which an individual is required to submit a complete set of fingerprints to the department for purposes of a criminal history background check under this section; and

(2) establish criteria for determining whether an individual passes the criminal history background check for the purposes of this section.

(d) After conducting a criminal history background check under this section, the department shall notify the relevant applicant or organization and the individual who is the subject of the criminal history background check as to whether the individual passed the criminal history background check.

Added by Acts 2015, 84th Leg., R.S., Ch. 301 (S.B. [339](#)), Sec. 1, eff. June 1, 2015.

Sec. 487.106. DUTY TO MAINTAIN ELIGIBILITY. A dispensing organization must maintain compliance at all times with the eligibility requirements described by Section [487.102](#).

Added by Acts 2015, 84th Leg., R.S., Ch. 301 (S.B. [339](#)), Sec. 1, eff. June 1, 2015.

Sec. 487.107. DUTIES RELATING TO DISPENSING PRESCRIPTION. (a) Before dispensing low-THC cannabis to a person for whom the low-THC cannabis is prescribed under Chapter [169](#), Occupations Code, the dispensing organization must verify that the prescription presented:

(1) is for a person listed as a patient in the compassionate-use registry;

(2) matches the entry in the compassionate-use registry with respect to the total amount of low-THC cannabis required to fill the prescription; and

(3) has not previously been filled by a dispensing organization as indicated by an entry in the compassionate-use registry.

(b) After dispensing low-THC cannabis to a patient for whom the low-THC cannabis is prescribed under Chapter [169](#), Occupations Code, the dispensing organization shall record in the compassionate-use registry the form and quantity of low-THC cannabis dispensed and the date and time of dispensation.

Added by Acts 2015, 84th Leg., R.S., Ch. 301 (S.B. [339](#)), Sec. 1, eff. June 1, 2015.

Sec. 487.108. LICENSE SUSPENSION OR REVOCATION. (a) The department may at any time suspend or revoke a license issued under this chapter if the department determines that the licensee has not maintained the eligibility requirements described by Section [487.102](#) or has failed to comply with a duty imposed under this chapter.

(b) The director shall give written notice to the dispensing organization of a license suspension or revocation under this section and the grounds for the suspension or revocation. The notice must be sent by certified mail, return receipt requested.

(c) After suspending or revoking a license issued under this chapter, the director may seize or place under seal all low-THC cannabis and drug paraphernalia owned or possessed by the dispensing organization. If the director orders the revocation of the license, a disposition may not be made of the seized or sealed low-THC cannabis or drug paraphernalia until the time for administrative appeal of the order has elapsed or until all appeals have been concluded. When a revocation order becomes final, all low-THC cannabis and drug paraphernalia may be forfeited to the state as provided under Subchapter E, Chapter [481](#).

(d) Chapter [2001](#), Government Code, applies to a proceeding under this section.

Added by Acts 2015, 84th Leg., R.S., Ch. 301 (S.B. [339](#)), Sec. 1, eff. June 1, 2015.

SUBCHAPTER D. REGISTRATION OF CERTAIN INDIVIDUALS

Sec. 487.151. REGISTRATION REQUIRED. (a) An individual who is a director, manager, or employee of a dispensing organization must apply for and obtain a registration under this section.

(b) An applicant for a registration under this section must:

- (1) be at least 18 years of age;
- (2) submit a complete set of fingerprints to the department in the manner required by department rule; and
- (3) pass a fingerprint-based criminal history background check as required by Section [487.105](#).

(c) A registration expires on the second anniversary of the date of the registration's issuance, unless suspended or revoked under rules adopted under this chapter.

Added by Acts 2015, 84th Leg., R.S., Ch. 301 (S.B. [339](#)), Sec. 1, eff. June 1, 2015.

SUBCHAPTER E. DUTIES OF COUNTIES AND MUNICIPALITIES

Sec. 487.201. COUNTIES AND MUNICIPALITIES MAY NOT PROHIBIT LOW-THC CANNABIS. A municipality, county, or other political subdivision may not enact, adopt, or enforce a rule, ordinance, order, resolution, or other regulation that prohibits the cultivation, production, dispensing, or possession of low-THC cannabis, as authorized by this chapter.

OCCUPATIONS CODE

TITLE 3. HEALTH PROFESSIONS

SUBTITLE B. PHYSICIANS

CHAPTER 169. AUTHORITY TO PRESCRIBE LOW-THC CANNABIS TO CERTAIN PATIENTS FOR COMPASSIONATE USE

Sec. 169.001. DEFINITIONS. In this chapter:

- (1) "Department" means the Department of Public Safety.
- (2) "Intractable epilepsy" means a seizure disorder in which the patient's seizures have been treated by two or more appropriately chosen and maximally titrated antiepileptic drugs that have failed to control the seizures.
- (3) "Low-THC cannabis" means the plant *Cannabis sativa* L., and any part of that plant or any compound, manufacture, salt, derivative, mixture, preparation, resin, or oil of that plant that contains:
 - (A) not more than 0.5 percent by weight of tetrahydrocannabinols;
and
 - (B) not less than 10 percent by weight of cannabidiol.
- (4) "Medical use" means the ingestion by a means of administration other than by smoking of a prescribed amount of low-THC cannabis by a person for whom low-THC cannabis is prescribed under this chapter.
- (5) "Smoking" means burning or igniting a substance and inhaling the smoke.

Added by Acts 2015, 84th Leg., R.S., Ch. 301 (S.B. [339](#)), Sec. 4, eff. June 1, 2015.

Sec. 169.002. PHYSICIAN QUALIFIED TO PRESCRIBE LOW-THC CANNABIS.

- (a) Only a physician qualified as provided by this section may prescribe low-THC cannabis in accordance with this chapter.
- (b) A physician is qualified to prescribe low-THC cannabis to a patient with intractable epilepsy if the physician:
 - (1) is licensed under this subtitle;
 - (2) dedicates a significant portion of clinical practice to the evaluation and treatment of epilepsy; and
 - (3) is certified:
 - (A) by the American Board of Psychiatry and Neurology in:
 - (i) epilepsy; or
 - (ii) neurology or neurology with special qualification in child neurology and is otherwise qualified for the examination for certification in epilepsy; or
 - (B) in neurophysiology by:
 - (i) the American Board of Psychiatry and Neurology; or
 - (ii) the American Board of Clinical Neurophysiology.

Added by Acts 2015, 84th Leg., R.S., Ch. 301 (S.B. [339](#)), Sec. 4, eff. June 1, 2015.

Sec. 169.003. PRESCRIPTION OF LOW-THC CANNABIS. A physician described by Section [169.002](#) may prescribe low-THC cannabis to alleviate a patient's seizures if:

- (1) the patient is a permanent resident of the state;
- (2) the physician complies with the registration requirements of Section [169.004](#); and
- (3) the physician certifies to the department that:
 - (A) the patient is diagnosed with intractable epilepsy;
 - (B) the physician determines the risk of the medical use of low-THC cannabis by the patient is reasonable in light of the potential benefit for the patient; and
 - (C) a second physician qualified to prescribe low-THC cannabis under Section [169.002](#) has concurred with the determination under Paragraph (B), and the second physician's concurrence is recorded in the patient's medical record.

Added by Acts 2015, 84th Leg., R.S., Ch. 301 (S.B. [339](#)), Sec. 4, eff. June 1, 2015.

Sec. 169.004. LOW-THC CANNABIS PRESCRIBER REGISTRATION. Before a physician qualified to prescribe low-THC cannabis under Section [169.002](#) may prescribe or renew a prescription for low-THC cannabis for a patient under this chapter, the physician must register as the prescriber for that patient in the compassionate-use registry maintained by the department under Section [487.054](#), Health and Safety Code.

The physician's registration must indicate:

- (1) the physician's name;
- (2) the patient's name and date of birth;
- (3) the dosage prescribed to the patient;
- (4) the means of administration ordered for the patient; and
- (5) the total amount of low-THC cannabis required to fill the patient's prescription.

X. Other Religious Cases

1. New Branches do not lose Status;and

Decisions made in Hierarchical Religious Structures are Binding in Civil Court
(via Presbyterian Church v. Hull Church 393 U.S. 440 (1969))

"The law knows no heresy, and is committed to the support of no dogma, the establishment of no sect. . . . All who unite themselves to such a body [the general church] do so with an implied consent to [its] government, and are bound to submit to it. But it would be a vain consent, and would lead to the total subversion of such religious bodies, if anyone aggrieved by one of their decisions could appeal to the secular courts and have them [*sic*] reversed. It is of the essence of these religious unions, and of their right to establish tribunals for the decision of questions arising among themselves, that those decisions should be binding in all cases of ecclesiastical cognizance, subject only to such appeals as the organism itself provides for."

2. Meaning of the Phrase: Sincere Religious Belief; and

All Religions deserve exemptions
(via Wisconsin v. Yoder U.S. 205 (1972))

"Within that phrase would come all sincere religious beliefs which are based upon a power or being, or upon a faith to which all else is subordinate or upon which all else is ultimately dependent. The test might be stated in these words: a sincere and meaningful belief which occupies in the life of its possessor a place parallel to that filled by the God

of those admittedly qualifying for the exemption comes within the statutory definition. This construction avoids imputing to Congress an intent to classify different religious beliefs, exempting some and excluding others, and is in accord with the well established congressional policy of equal treatment for those whose opposition to service is grounded in their religious tenets."

XI. The Controlled Substances Act (CSA) is Void

1. The Court may not operate a Violation of Rights

Brown v. New Jersey 175 U.S. 172 (1899)

"The state has full control over the procedure in its courts, both in civil and criminal cases, subject only to the qualification that such procedure must not work a denial of fundamental rights or conflict with specific and applicable provisions of the federal Constitution. Ex Parte Reggel, [114 U. S. 642](#); Iowa Central Railway v. Iowa, [160 U. S. 389](#); Chicago, Burlington & Quincy Railroad v. Chicago, [166 U. S. 226](#)."

2. Laws Used Discriminatorily are Unconstitutional and Void

(via Yick Wo v. Hopkins 118 U.S. 356 (1886))

"The same principle has been more freely extended to the *quasi*-legislative acts of inferior municipal bodies, in respect to which it is an ancient jurisdiction of judicial tribunals to pronounce upon the reasonableness and consequent validity of their by laws. In respect to these, it was the doctrine that every bylaw must be reasonable, not inconsistent with the charter of the corporation, nor with any statute of Parliament, nor with the general principles of the common law of the land, particularly those having relation to the liberty of the subject or the rights of private property. Dillon on Municipal Corporations, 3d ed., § 319, and cases cited in notes. Accordingly, in the case of *The State of Ohio ex rel. &c. v. The Cincinnati Gas-Light and Coke Company*, 18 Ohio St. 232, 300, an ordinance of the city council purporting to fix the price to be charged for gas, under an authority of law giving discretionary power to do so, was held to be bad, if passed in bad faith, fixing an unreasonable price, for the fraudulent purpose of compelling the gas company to submit to an unfair appraisement of their works. And a similar question, very pertinent to the one in the present cases, was decided by the Court of Appeals of Maryland in the case of the *City of Baltimore v. Radecke*, 49 Maryland 217. In that case, the defendant had erected and used a steam engine in the prosecution of his business as a carpenter and box-maker in the city of Baltimore, under

a permit from the mayor and city council, which contained a condition that the engine was "to be removed after six months' notice to that effect from the mayor." After such notice and refusal to conform to it, a suit was instituted to recover the penalty provided by the ordinance, to restrain the prosecution of which a bill in equity was filed. The court holding the opinion that

"there may be a case in which an ordinance, passed under grants of power like those we have cited, is so clearly unreasonable, so arbitrary, oppressive, or partial, as to raise the presumption that the legislature never intended to confer the power to pass it, and to justify the courts in interfering and setting it aside as a plain abuse of authority," it proceeds to speak, with regard to the ordinance in question, in relation to the use of steam engines, as follows:

"It does not profess to prescribe *regulations* for their construction, location, or use, nor require such precautions and safeguards to be provided by those who own and use them as are best calculated to render them less dangerous to life and property, nor does it restrain their use in box factories and other similar establishments within certain defined limits, nor in any other way attempt to promote their safety and security without destroying their usefulness. But it commits to the unrestrained will of a single public officer the power to notify every person who now employs a steam engine in the prosecution of any business in the city of Baltimore to cease to do so, and, by providing compulsory fines for every day's disobedience of such notice and order of removal, renders his power over the use of steam in that city practically absolute, so that he may prohibit its use altogether. But if he should not choose to do this, but only to act in particular cases, there is nothing in the ordinance to guide or control his action. It lays down *no rules* by which its *impartial execution* can be secured or partiality and oppression prevented. It is clear that giving and enforcing these notices may, and quite likely will, bring ruin to the business of those against whom they are directed, while others, from whom they are withheld, may be actually benefited by what is thus done to their neighbors; and, when we remember that this action or nonaction may proceed from enmity or prejudice, from partisan zeal or animosity, from favoritism and other improper influences and motives easy of concealment and difficult to be detected and exposed, it becomes unnecessary to suggest or to comment upon the injustice capable of being brought under cover of such a power, for that becomes apparent to everyone who gives to the subject a moment's consideration. In fact, an ordinance which clothes a single individual with such power hardly falls within the *domain of law*, and we are constrained to pronounce it inoperative and void."

3. Laws are not more powerful than Constitutions/Amendments

Hilton v. Guyot 159 U.S. 113 (1895)

“No law has any effect, of its own force, beyond the limits of the sovereignty from which its authority is derived.”

Marbury v. Madison 5 U.S. 137 (1803)

“The question whether an act repugnant to the Constitution can become the law of the land is a question deeply interesting to the United States, but, happily, not of an intricacy proportioned to its interest. It seems only necessary to recognise certain principles, supposed to have been long and well established, to decide it.

That the people have an original right to establish for their future government such principles as, in their opinion, shall most conduce to their own happiness is the basis on which the whole American fabric has been erected. The exercise of this original right is a very great exertion; nor can it nor ought it to be frequently repeated. The principles, therefore, so established are deemed fundamental. And as the authority from which they proceed, is supreme, and can seldom act, they are designed to be permanent.

This original and supreme will organizes the government and assigns to different departments their respective powers. It may either stop here or establish certain limits not to be transcended by those departments.

The Government of the United States is of the latter description. The powers of the Legislature are defined and limited; and that those limits may not be mistaken or forgotten, the Constitution is written. To what purpose are powers limited, and to what purpose is that limitation committed to writing, if these limits may at any time be passed by those intended to be restrained? The distinction between a government with limited and unlimited powers is abolished if those limits do not confine the persons on whom they are imposed, and if acts prohibited and acts allowed are of equal obligation. It is a proposition too plain to be contested that the Constitution controls any legislative act repugnant to it, or that the Legislature may alter the Constitution by an ordinary act.

Between these alternatives there is no middle ground. The Constitution is either a superior, paramount law, unchangeable by ordinary means, or it is on a level with ordinary legislative acts, and, like other acts, is alterable when the legislature shall please to alter it.

If the former part of the alternative be true, then a legislative act contrary to the Constitution is not law; if the latter part be true, then written Constitutions are absurd attempts on the part of the people to limit a power in its own nature illimitable. Certainly all those who have framed written Constitutions contemplate them as forming the fundamental and paramount law of the nation, and consequently the theory of every such government must be that an act of the Legislature repugnant to the Constitution is void.

This theory is essentially attached to a written Constitution, and is consequently to be considered by this Court as one of the fundamental principles of our society. It is not, therefore, to be lost sight of in the further consideration of this subject.

If an act of the Legislature repugnant to the Constitution is void, does it, notwithstanding its invalidity, bind the Courts and oblige them to give it effect? Or, in other words, though it be not law, does it constitute a rule as operative as if it was a law? This would be to overthrow in fact what was established in theory, and would seem, at first view, an absurdity too gross to be insisted on. It shall, however, receive a more attentive consideration.

It is emphatically the province and duty of the Judicial Department to say what the law is. Those who apply the rule to particular cases must, of necessity, expound and interpret that rule. If two laws conflict with each other, the Courts must decide on the operation of each."

Exhibit 18

By notice dated December 21, 2015, and published in the Federal Register on December 29, 2015, 80 FR 81367, Johnson Matthey, Inc., Pharmaceutical Materials, 2003 Nolte Drive, West Deptford, New Jersey 08066-1742 applied to be registered as an importer of certain basic classes of controlled substances. Comments and request for hearings on applications to import narcotic raw material are not appropriate. 72 FR 3417, (January 25, 2007). Also no comments or objections were submitted for this notice.

The DEA has considered the factors in [21 U.S.C. 823](#), [952\(a\)](#) and [958\(a\)](#) and determined that the registration of Johnson Matthey, Inc. to import the basic classes of controlled substances is consistent with the public interest and with United States obligations under international treaties, conventions, or protocols in effect on May 1, 1971. The DEA investigated the company's maintenance of effective controls against diversion by inspecting and testing the company's physical security systems, verifying the company's compliance with state and local laws, and reviewing the company's background and history.

Therefore, pursuant to [21 U.S.C. 952\(a\)](#) and [958\(a\)](#), and in accordance with [21 CFR 1301.34](#), the above-named company is granted registration as an importer of the following basic classes of controlled substances:

Controlled Substance	Schedule
----------------------	----------

Coca Leaves (9040)	II
Thebaine (9333)	II
Opium, raw (9600)	II
Noroxymorphone (9668)	II
Poppy Straw Concentrate (9670)	II
Fentanyl (9801)	II

The company plans to import thebaine derivatives and fentanyl as reference standards.

The company plans to import the remaining listed controlled substances as raw materials, to be used in the manufacture of bulk controlled substances, for distribution to its customers. Placement of these drug codes onto the company's registration does not translate into automatic approval of subsequent permit applications to import controlled substances.

Approval of permit applications will occur only when the registrant's business activity is consistent with what is authorized under [21 U.S.C. 952\(a\)\(2\)](#). Authorization will not extend to the import of FDA approved or non-approved finished dosage forms for commercial sale.

Dated: April 11, 2016.

Louis J. Milione,
Deputy Assistant Administrator.

Exhibit 19

The Attorney General has delegated her authority under the Controlled Substances Act to the Administrator of the Drug Enforcement Administration (DEA), 28 CFR 0.100(b).

Authority to exercise all necessary functions with respect to the promulgation and implementation of [21 CFR part 1301](#), incident to the registration of manufacturers, distributors, dispensers, importers, and exporters of controlled substances (other than final orders in connection with suspension, denial, or revocation of registration) has been redelegated to the Deputy Assistant Administrator of the DEA Office of Diversion Control ("Deputy Assistant Administrator") pursuant to section 7 of 28 CFR part 0, appendix to subpart R.

In accordance with [21 CFR 1301.33\(a\)](#), this is notice that on September 3, 2015, Johnson Matthey, Inc., Pharmaceuticals Materials, 900 River Road, Conshohocken, Pennsylvania 19428 applied to be

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registered as a bulk manufacturer of the following basic classes of controlled substances:

Controlled Substance	Schedule
Gamma Hydroxybutyric Acid (2010)	I
Amphetamine (1100)	II
Methylphenidate (1724)	II
Codeine (9050)	II
Oxycodone (9143)	II
Diphenoxylate (9170)	II
Hydrocodone (9193)	II
Meperidine (9230)	II
Methadone (9250)	II
Methadone intermediate (9254)	II
Morphine (9300)	II
Thebaine (9333)	II

The company plans to manufacture the listed controlled substances in bulk for distribution and sale to its customers. The thebaine (9333) will be used to manufacture other controlled substances for sale in bulk to its customers.

Dated: January 13, 2016.

Louis J. Milione,
Deputy Assistant Administrator.

Article XVIII, Section 16: Personal Use and Regulation of Marijuana, Colorado
Constitution

(1) PURPOSE AND FINDINGS. (a) In the interest of the efficient use of law enforcement resources, enhancing revenue for public purposes, and individual freedom, the people of the state of Colorado find and declare that the use of marijuana should be legal for persons twenty-one years of age or older and taxed in a manner similar to alcohol. (b) In the interest of the health and public safety of our citizenry, the people of the state of Colorado further find and declare that marijuana should be regulated in a manner similar to alcohol so that: (I) Individuals will have to show proof of age before purchasing marijuana; (II) Selling, distributing, or transferring marijuana to minors and other individuals under the age of twenty-one shall remain illegal; (III) Driving under the influence of marijuana shall remain illegal; (IV) Legitimate, taxpaying business people, and not criminal actors, will conduct sales of marijuana; and (V) Marijuana sold in this state will be labeled and subject to additional regulations to ensure that consumers are informed and protected. (c) In the interest of enacting rational policies for the treatment of all variations of the cannabis plant, the people of Colorado further find and declare that industrial hemp should be regulated separately from strains of cannabis with higher delta-9 tetrahydrocannabinol (THC) concentrations. (d) The people of the state of Colorado further find and declare that it is necessary to ensure consistency and fairness in the application of this section throughout the state and that, therefore, the matters addressed by this section are, except as specified herein, matters of statewide concern. (2) DEFINITIONS. As used in this section, unless the context otherwise requires, (a) "Colorado Medical Marijuana Code" means article 43.3 of title 12, Colorado Revised Statutes. (b) "Consumer" means a person twenty-one years of age or older who purchases marijuana or marijuana products for personal use by persons twenty-one years of age or older, but not for resale to others. (c) "Department" means the department of revenue or its successor agency. (d) "Industrial hemp" means the plant of the genus cannabis and any part of such plant, whether growing or not, with a delta-9 tetrahydrocannabinol concentration that does not exceed three-tenths percent on a dry weight basis. (e) "Locality" means a county, municipality, or city and county. (f) "Marijuana" or "marihuana" means all parts of the plant of the genus cannabis whether growing or not, the seeds thereof, the resin extracted from any part of the plant, and every compound, manufacture, salt, derivative, mixture, or preparation of the plant, its seeds, or its resin, including marihuana concentrate. "Marijuana" or "marihuana" does not include industrial hemp, nor does it include fiber produced from the stalks, oil, or cake made from the seeds of the plant, sterilized seed of the plant which is incapable of germination, or the weight of any other ingredient combined with marijuana to prepare topical or oral administrations, food, drink, or other product. (g)

"Marijuana accessories" means any equipment, products, or materials of any kind which are used, intended for use, or designed for use in planting, propagating, cultivating, growing, harvesting, composting, manufacturing, compounding, converting, producing, processing, preparing, testing, analyzing, packaging, repackaging, storing, vaporizing, or containing marijuana, or for ingesting, inhaling, or otherwise introducing marijuana into the human body. (h) "Marijuana cultivation facility" means an entity licensed to cultivate, prepare, and package marijuana and sell marijuana to retail marijuana stores, to marijuana product manufacturing facilities, and to other marijuana cultivation facilities, but not to consumers. (i) "Marijuana establishment" means a marijuana cultivation facility, a marijuana testing facility, a marijuana product manufacturing facility, or a retail marijuana store. (j) "Marijuana product manufacturing facility" means an entity licensed to purchase marijuana; manufacture, prepare, and package marijuana products; and sell marijuana and marijuana products to other marijuana product manufacturing facilities and to retail marijuana stores, but not to consumers. (k) "Marijuana products" means concentrated marijuana products and marijuana products that are comprised of marijuana and other ingredients and are intended for use or consumption, such as, but not limited to, edible products, ointments, and tinctures. (l) "Marijuana testing facility" means an entity licensed to analyze and certify the safety and potency of marijuana. (m) "Medical marijuana center" means an entity licensed by a state agency to sell marijuana and marijuana products pursuant to section 14 of this article and the Colorado Medical Marijuana Code. (n) "Retail marijuana store" means an entity licensed to purchase marijuana from marijuana cultivation facilities and marijuana and marijuana products from marijuana product manufacturing facilities and to sell marijuana and marijuana products to consumers. (o) "Unreasonably impracticable" means that the measures necessary to comply with the regulations require such a high investment of risk, money, time, or any other resource or asset that the operation of a marijuana establishment is not worthy of being carried out in practice by a reasonably prudent businessperson. (3) PERSONAL USE OF MARIJUANA. Notwithstanding any other provision of law, the following acts are not unlawful and shall not be an offense under Colorado law or the law of any locality within Colorado or be a basis for seizure or forfeiture of assets under Colorado law for persons twenty-one years of age or older: (a) Possessing, using, displaying, purchasing, or transporting marijuana accessories or one ounce or less of marijuana. (b) Possessing, growing, processing, or transporting no more than six marijuana plants, with three or fewer being mature, flowering plants, and possession of the marijuana produced by the plants on the premises where the plants were grown, provided that the growing takes place in an enclosed, locked space, is not conducted openly or publicly, and is not made available for sale. (c) Transfer of one ounce or less of marijuana without remuneration to a person who is twenty

one years of age or older. (d) Consumption of marijuana provided that nothing in this section shall permit consumption that is conducted openly and publicly or in a manner that endangers others. (e) Assisting another person who is twenty-one years of age or older in any of the acts described in paragraphs (a) through (d) of this subsection. (4)

LAWFUL OPERATION OF MARIJUANA-RELATED FACILITIES. Notwithstanding any other provision of law, the following acts are not unlawful and shall not be an offense under Colorado law or be a basis for seizure or forfeiture of assets under Colorado law

for persons twenty-one years of age or older: (a) Manufacture, possession, or purchase of marijuana accessories or the sale of marijuana accessories to a person who is twenty-one years of age or older. (b) Possessing, displaying, or transporting marijuana or marijuana products; purchase of marijuana from a marijuana cultivation facility; purchase of marijuana or marijuana products from a marijuana product manufacturing facility; or sale of marijuana or marijuana products to consumers, if the person conducting the activities described in this paragraph has obtained a current, valid license to operate a retail marijuana store or is acting in his or her capacity as an owner, employee or agent of a licensed retail marijuana store. (c) Cultivating, harvesting, processing, packaging, transporting, displaying, or possessing marijuana; delivery or transfer of marijuana to a marijuana testing facility; selling marijuana to a marijuana cultivation facility, a marijuana product manufacturing facility, or a retail marijuana store; or the purchase of marijuana from a marijuana cultivation facility, if the person conducting the activities described in this paragraph has obtained a current, valid license to operate a marijuana cultivation facility or is acting in his or her capacity as an owner, employee, or agent of a licensed marijuana cultivation facility. (d)

Packaging, processing, transporting, manufacturing, displaying, or possessing marijuana or marijuana products; delivery or transfer of marijuana or marijuana products to a marijuana testing facility; selling marijuana or marijuana products to a retail marijuana store or a marijuana product manufacturing facility; the purchase of marijuana from a marijuana cultivation facility; or the purchase of marijuana or marijuana products from a marijuana product manufacturing facility, if the person conducting the activities described in this paragraph has obtained a current, valid license to operate a marijuana product manufacturing facility or is acting in his or her capacity as an owner, employee, or agent of a licensed marijuana product manufacturing facility. (e) Possessing, cultivating, processing, repackaging, storing, transporting, displaying, transferring or delivering marijuana or marijuana products if the person has obtained a current, valid license to operate a marijuana testing facility or is acting in his or her capacity as an owner, employee, or agent of a licensed marijuana testing facility. (f) Leasing or otherwise allowing the use of property owned, occupied or controlled by any person, corporation or other entity for any of the activities conducted lawfully in accordance with paragraphs (a) through (e) of

this subsection. (5) REGULATION OF MARIJUANA. (a) Not later than July 1, 2013, the department shall adopt regulations necessary for implementation of this section.

Such regulations shall not prohibit the operation of marijuana establishments, either expressly or through regulations that make their operation unreasonably impracticable.

Such regulations shall include: (I) Procedures for the issuance, renewal, suspension, and revocation of a license to operate a marijuana establishment, with such procedures subject to all requirements of article 4 of title 24 of the Colorado Administrative

Procedure Act or any successor provision; (II) A schedule of application, licensing and renewal fees, provided, application fees shall not exceed five thousand dollars, with this

upper limit adjusted annually for inflation, unless the department determines a greater fee is necessary to carry out its responsibilities under this section, and provided further, an entity that is licensed under the Colorado Medical Marijuana Code to cultivate or sell

marijuana or to manufacture marijuana products at the time this section takes effect and that chooses to apply for a separate marijuana establishment license shall not be

required to pay an application fee greater than five hundred dollars to apply for a license to operate a marijuana establishment in accordance with the provisions of this section; (III) Qualifications for licensure that are directly and demonstrably related to

the operation of a marijuana establishment; (IV) Security requirements for marijuana establishments; (V) Requirements to prevent the sale or diversion of marijuana and marijuana products to

persons under the age of twenty-one; (VI) Labeling requirements for marijuana and marijuana products sold or distributed by a marijuana establishment; (VII) Health and

safety regulations and standards for the manufacture of marijuana products and the cultivation of marijuana; (VIII) Restrictions on the advertising and display of marijuana and marijuana products; and (IX) Civil penalties for the failure to comply with

regulations made pursuant to this section. (b) In order to ensure the most secure, reliable, and accountable system for the production and distribution of marijuana and marijuana products in accordance with this subsection, in any competitive application process the department shall have as a primary consideration whether an applicant:

(I) Has prior experience producing or distributing marijuana or marijuana products pursuant to section 14 of this article and the Colorado Medical Marijuana Code in the locality in which the applicant seeks to operate a marijuana establishment; and (II)

Has, during the experience described in subparagraph (I), complied consistently with section 14 of this article, the provisions of the Colorado Medical Marijuana Code and conforming regulations. (c) In order to ensure that individual privacy is protected,

notwithstanding paragraph (a), the department shall not require a consumer to provide a retail marijuana store with personal information other than government-issued

identification to determine the consumer's age, and a retail marijuana store shall not be required to acquire and record personal information about consumers other than

information typically acquired in a financial transaction conducted at a retail liquor store.

(d) The general assembly shall enact an excise tax to be levied upon marijuana sold or otherwise transferred by a marijuana cultivation facility to a marijuana product manufacturing facility or to a retail marijuana store at a rate not to exceed fifteen percent prior to January 1, 2017 and at a rate to be determined by the general assembly thereafter, and shall direct the department to establish procedures for the collection of all taxes levied. Provided, the first forty million dollars in revenue raised annually from any such excise tax shall be credited to the

Public School Capital Construction Assistance Fund created by article 43.7 of title 22, C.R.S., or any successor fund dedicated to a similar purpose. Provided further, no such excise tax shall be levied upon marijuana intended for sale at medical marijuana centers pursuant to section 14 of this article and the Colorado Medical Marijuana Code.

(e) Not later than October 1, 2013, each locality shall enact an ordinance or regulation specifying the entity within the locality that is responsible for processing applications submitted for a license to operate a marijuana establishment within the boundaries of the locality and for the issuance of such licenses should the issuance by the locality become necessary because of a failure by the department to adopt regulations pursuant to paragraph (a) or because of a failure by the department to process and issue licenses as required by paragraph (g). (f) A locality may enact ordinances or regulations, not in conflict with this section or with regulations or legislation enacted pursuant to this section, governing the time, place, manner and number of marijuana establishment operations; establishing procedures for the issuance, suspension, and revocation of a license issued by the locality in accordance with paragraph (h) or (i), such procedures to be subject to all requirements of article 4 of title 24 of the Colorado Administrative Procedure Act or any successor provision; establishing a schedule of annual operating, licensing, and application fees for marijuana establishments, provided, the application fee shall only be due if an application is submitted to a locality in accordance with paragraph (i) and a licensing fee shall only be due if a license is issued by a locality in accordance with paragraph (h) or (i); and establishing civil penalties for violation of an ordinance or regulation governing the time, place, and manner of a marijuana establishment that may operate in such locality. A locality may prohibit the operation of marijuana cultivation facilities, marijuana product manufacturing facilities, marijuana testing facilities, or retail marijuana stores through the enactment of an ordinance or through an initiated or referred measure; provided, any initiated or referred measure to prohibit the operation of marijuana cultivation facilities, marijuana product manufacturing facilities, marijuana testing facilities, or retail marijuana stores must appear on a general election ballot during an even numbered year. (g) Each application for an annual license to operate a marijuana establishment shall be submitted to the department. The department shall: (I) Begin accepting and

processing applications on October 1, 2013; (II) Immediately forward a copy of each application and half of the license application fee to the locality in which the applicant desires to operate the marijuana establishment;

(III) Issue an annual license to the applicant between forty-five and ninety days after receipt of an application unless the department finds the applicant is not in compliance with regulations enacted pursuant to paragraph (a) or the department is notified by the relevant locality that the applicant is not in compliance with ordinances and regulations made pursuant to paragraph (f) and in effect at the time of application, provided, where a locality has enacted a numerical limit on the number of marijuana establishments and a greater number of applicants seek licenses, the department shall solicit and consider input from the locality as to the locality's preference or preferences for licensure; and (IV) Upon denial of an application, notify the applicant in writing of the specific reason for its denial. (h) If the department does not issue a license to an applicant within ninety days of receipt of the application filed in accordance with paragraph (g) and does not notify the applicant of the specific reason for its denial, in writing and within such time period, or if the department has adopted regulations pursuant to paragraph (a) and has accepted applications pursuant to paragraph (g) but has not issued any licenses by January 1, 2014, the applicant may resubmit its application directly to the locality, pursuant to paragraph (e), and the locality may issue an annual license to the applicant. A locality issuing a license to an applicant shall do so within ninety days of receipt of the resubmitted application unless the locality finds and notifies the applicant that the applicant is not in compliance with ordinances and regulations made pursuant to paragraph (f) in effect at the time the application is resubmitted and the locality shall notify the department if an annual license has been issued to the applicant. If an application is submitted to a locality under this paragraph, the department shall forward to the locality the application fee paid by the applicant to the department upon request by the locality. A license issued by a locality in accordance with this paragraph shall have the same force and effect as a license issued by the department in accordance with paragraph (g) and the holder of such license shall not be subject to regulation or enforcement by the department during the term of that license. A subsequent or renewed license may be issued under this paragraph on an annual basis only upon resubmission to the locality of a new application submitted to the department pursuant to paragraph (g). Nothing in this paragraph shall limit such relief as may be available to an aggrieved party under section 24-4-104, C.R.S., of the Colorado Administrative Procedure Act or any successor provision. (i) If the department does not adopt regulations required by paragraph (a), an applicant may submit an application directly to a locality after October 1, 2013 and the locality may issue an annual license to the applicant. A locality issuing a license to an applicant shall do so within ninety days of receipt of the application unless it finds and notifies the applicant that the

applicant is not in compliance with ordinances and regulations made pursuant to paragraph (f) in effect at the time of application and shall notify the department if an annual license has been issued to the applicant. A license issued by a locality in accordance with this paragraph shall have the same force and effect as a license issued by the department in accordance with paragraph (g) and the holder of such license shall not be subject to regulation or enforcement by the department during the term of that license. A subsequent or renewed license may be issued under this paragraph on an annual basis if the department has not adopted regulations required by paragraph (a) at least ninety days prior to the date upon which such subsequent or renewed license would be effective or if the department has adopted regulations pursuant to paragraph (a) but has not, at least ninety days after the adoption of such regulations, issued licenses pursuant to paragraph (g). (j) Not later than July 1, 2014, the general assembly shall enact legislation governing the cultivation, processing and sale of industrial hemp.

(6) EMPLOYERS, DRIVING, MINORS AND CONTROL OF PROPERTY. (a) Nothing in this section is intended to require an employer to permit or accommodate the use, consumption, possession, transfer, display, transportation, sale or growing of marijuana in the workplace or to affect the ability of employers to have policies restricting the use of marijuana by employees. (b) Nothing in this section is intended to allow driving under the influence of marijuana or driving while impaired by marijuana or to supersede statutory laws related to driving under the influence of marijuana or driving while impaired by marijuana, nor shall this section prevent the state from enacting and imposing penalties for driving under the influence of or while impaired by marijuana. (c) Nothing in this section is intended to permit the transfer of marijuana, with or without remuneration, to a person under the age of twenty-one or to allow a person under the age of twenty-one to purchase, possess, use, transport, grow, or consume marijuana. (d) Nothing in this section shall prohibit a person, employer, school, hospital, detention facility, corporation or any other entity who occupies, owns or controls a property from prohibiting or otherwise regulating the possession, consumption, use, display, transfer, distribution, sale, transportation, or growing of marijuana on or in that property.

(7) MEDICAL MARIJUANA PROVISIONS UNAFFECTED. Nothing in this section shall be construed: (a) To limit any privileges or rights of a medical marijuana patient, primary caregiver, or licensed entity as provided in section 14 of this article and the Colorado Medical Marijuana Code; (b) To permit a medical marijuana center to distribute marijuana to a person who is not a medical marijuana patient; (c) To permit a medical marijuana center to purchase marijuana or marijuana products in a manner or from a source not authorized under the Colorado Medical Marijuana Code; (d) To permit any medical marijuana center licensed pursuant to section 14 of this article and the Colorado Medical Marijuana Code to operate on the same premises as a retail marijuana store; or (e) To discharge the

department, the Colorado Board of Health, or the Colorado Department of Public Health and Environment from their statutory and constitutional duties to regulate medical marijuana pursuant to section 14 of this article and the Colorado Medical Marijuana Code. (8) SELF-EXECUTING, SEVERABILITY, CONFLICTING PROVISIONS. All provisions of this section are self-executing except as specified herein, are severable, and, except where otherwise indicated in the text, shall supersede conflicting state statutory, local charter, ordinance, or resolution, and other state and local provisions. (9) EFFECTIVE DATE. Unless otherwise provided by this section, all provisions of this section shall become effective upon official declaration of the vote hereon by proclamation of the governor, pursuant to section 1(4) of article V.

Exhibit 21

During the Soviet Era, and especially at the end when the US and the Soviet Union were in the middle of the Cold War, Scientific Discoveries on each side became more isolated from each other and there was a split in the Scientific Communities of the East and the West and the directions of their Scientific Research. And this split has lasted in to today. An example of this is the Russian Perspective on Olympic Athletes Doping. Over the last 10-20 years there are a large number of Molecules that have become listed as banned for Olympic Athletes, but in Russia they prescribe these kinds of Molecules to people all across the country. Another example is Piracetam, which in the US not considered a Medicine, but it is known to improve cognitive function, and is prescribed in Russia to improve Cognitive function.

This paper explains some of the Pharmacological Contributions of the Soviet Union
<http://www.annualreviews.org/doi/abs/10.1146/annurev.pa.08.040168.000325?journalCode=pharmtox.1>

This paper explains some of the Physiological Contributions of the Soviet Union
<http://www.ncbi.nlm.nih.gov/pubmed/11896000>

And because the US had recently dropped a Nuclear Bomb on Japan, the Soviet Union also did research on the role of Tryptamines as Anti-Radiological medicines which also lead to Research into the role of Tryptamines, such as Melatonin, in the brain
[http://www.redjournal.org/article/S0360-3016\(04\)00246-9/abstract?cc=y=](http://www.redjournal.org/article/S0360-3016(04)00246-9/abstract?cc=y=)

A lot of people have heard of Government projects where Psychedelics were tested for different purposes. A well Documented example is Edgewood Arsenal, where an array of Psychoactive Molecules were tested on volunteers in the Airforce. But many people

do not realize that during this time Psychedelics were being used in Psychiatry with great success. The best example is MDMA, now called Ecstasy, which during the 70s was considered a Miracle drug for all kinds of Psychiatric treatment.

These research papers explain the use of Hallucinogenics in Psychiatric therapy

<http://www.ncbi.nlm.nih.gov/pubmed/7891058>

<http://www.ncbi.nlm.nih.gov/pubmed/9754835>

<http://www.ncbi.nlm.nih.gov/pubmed/16086535>

This paper explains extremely recent research (Published in 2016) into MDMA and Psilocybin in Psychiatric therapy

<http://www.ncbi.nlm.nih.gov/pubmed/27067625>

This paper shows that Psychedelics like Psilocybin and Mescaline do not cause long term Mental health problems

<http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3747247/>

This paper shows where Native Americans who use Peyote (Mescaline) regularly were tested against Alcoholics, and the Native Americans showed no deficit in neuropsychological performance, while the Alcoholics showed a strong deficit

<http://www.ncbi.nlm.nih.gov/pubmed/16271313>

Exhibit 22

Many people believe that once you have all your Brain Cells, that's it, and from there on all you can do is lose them. But that is actually not true. The recent discovery of Neurogenesis shows us that new Brain Cells (Neurons) can be formed in the Human brain, and the discovery of Synaptogenesis shows that new pathways can be created between those Neurons. The difference between these things is that Neurons are the actual Brain Cell, while Synapses are the electrochemical signals of the Neuron. When you hear a song and it reminds you of what you were doing the first time you heard that song, this is called Cognition. Cogs are the gears in a machine, so Cognition can be pictures as gears in a machine, where one gear is attached to something that makes it spin, but the other gears spin because the first gear is spinning them, and that can cause a whole cluster of gears to spin. That is Cognition in your brain also, the first spark causes a series of other sparks, and as in the example you hear a song and remember what you were doing the first time you heard it. This happens along a pathway of Neurons via their Synaptic signaling, the Synapses create the pathways, so

with Neurogenesis you have more Neurons and with Synaptogenesis you can create new pathways.

In your brain you have an Endocannabinoid System (ECS), and it has shown to play an important role in different Neural functions. These papers explain some of the things the ECS plays a role in, including Neurogenesis

http://link.springer.com/chapter/10.1007%2F978-0-387-74349-3_12
<http://www.jci.org/articles/view/25509>

This paper includes a full explanation of what Neurogenesis is
<http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3106107/>

It has also been shown that the Endocannabinoid called 2-AG has been proven to be able to protect the brain from brain damage in the case of a Traumatic Brain Injury and can stop brain swelling.

This study was done in 2001 and shows that it protects the brain from brain damage
<http://www.ncbi.nlm.nih.gov/pubmed/11586361>

This study was done in 2003 and shows that it can reverse brain swelling (Edema) which happens to people in a Coma and is a major cause of death in a Coma, or after a Stroke.

<http://www.ncbi.nlm.nih.gov/pubmed/14753451>

This study also shows that it can reverse brain swelling
<http://www.ncbi.nlm.nih.gov/pubmed/15729296>

There is even a Patent for 2-AG that says what it does
<https://www.google.com/patents/WO2001097793A2?cl=en>

These research papers explain how Cannabinoids act as a Neuroprotectant
<http://www.ncbi.nlm.nih.gov/pubmed/15837565>
<http://science.sciencemag.org/content/302/5642/84>

Synaptogenesis is connected to Neurogenesis in Cognition, but they are 2 completely different things. Synaptogenesis has to do with Dendrites. Dendrites are arms that extend from your Neurons and allow the electrochemically signaling between cells. Synaptogenesis is achieved using Ampakines.

This Paper explains how Ampakines create new pathways within hours, and how Ampakines could eventually replace MAOIs and SSRIs.

<http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3622786/>

<http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3195863/>

Exhibit 23

Here are some examples of Hindus, just to show that you do not have to be from India to be Hindu:

Tulsi Gabbard
Julia Roberts
John Coltrane
Elizabeth Gilbert
MIA
George Harrison
Jerry Garcia
Ravi Coltrane
Alice Coltrane
Ricky Williams
JD Salinger
John McLaughlin

Exhibit 24

"This life of yours which you are living is not merely a piece of this entire existence, but in a certain sense the whole; only this whole is not constituted that it can be surveyed in one single glance. This, as we know, is that sacred, mystic formula which is yet really so simple and so clear; tat tvam asi, this is you. Or, again, in such words as 'I am in the east and west, I am above and below, I am this entire world'"

-Erwin Schrodinger

"All perceptible matter comes from... a primary substance, or tenuity beyond conception, filling all space, the Akasha (आकाश) or luminiferous ether, which is acted upon by the life giving Prana (प्राण) or creative force, calling into existence, in never-ending cycles all things and phenomena."

-Nikola Tesla

Exhibit 25

Applications To Become Registered Under the Controlled Substances Act To
Manufacture Marijuana To Supply Researchers in the United States

AGENCY:

Drug Enforcement Administration, Department of Justice.

ACTION:

Policy statement.

SUMMARY:

To facilitate research involving marijuana and its chemical constituents, DEA is adopting a new policy that is designed to increase the number of entities registered under the Controlled Substances Act (CSA) to grow (manufacture) marijuana to supply legitimate researchers in the United States. This policy statement explains how DEA will evaluate applications for such registration consistent with the CSA and the obligations of the United States under the applicable international drug control treaty.

DATES:

August 12, 2016.

Start Further Info

FOR FURTHER INFORMATION CONTACT:

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Address: 8701 Morrisette Drive, Springfield, Virginia 22152; Telephone: (202)
598-6812.

End Further Info End Preamble Start Supplemental Information

SUPPLEMENTARY INFORMATION:

Background

Reasons for This Policy Statement

There is growing public interest in exploring the possibility that marijuana or its chemical constituents may be used as potential treatments for certain medical conditions. The Federal Food, Drug and Cosmetic Act requires that before a new drug is allowed to enter the U.S. market, it must be demonstrated through adequate and well-controlled clinical trials to be both safe and effective for its intended uses. Congress long ago established this process, recognizing that it was essential to protect the health and welfare of the American people.

Although no drug product made from marijuana has yet been shown to be safe and effective in such clinical trials, DEA—along with the Food and Drug Administration (FDA) and the National Institutes of Health (NIH)—fully supports expanding research into the potential medical utility of marijuana and its chemical constituents.^[1]

There are a variety of factors that influence whether and to what extent such research takes place. Some of the key factors—such as funding—are beyond DEA's control.^[2] However, one of the ways DEA can help to facilitate research involving marijuana is to take steps, within the framework of the CSA and U.S. treaty obligations, to increase the lawful supply of marijuana available to researchers.

For nearly 50 years, the United States has relied on a single grower to produce marijuana used in research. This grower operates under a contract with the National Institute on Drug Abuse (NIDA). This longstanding arrangement has historically been considered by the U.S. Government to be the best way to satisfy our nation's obligations under the applicable international drug control treaty, as discussed in more detail below. For most of the nearly 50 years that this single marijuana grower arrangement has been in existence, the demand for research-grade marijuana in the United States was relatively limited—and the single grower was able to meet such limited demand.

However, in recent years, there has been greater public interest in expanding marijuana-related research, particularly with regard to certain chemical constituents in the plant known as cannabinoids.

The term “cannabinoids” generally refers to those chemicals unique to the cannabis plant (marijuana).^[3] To date, more than 100 different cannabinoids have been found in the plant. One such cannabinoid—known as cannabidiol or CBD—has received increased attention in recent years. Although the effects of CBD are not yet fully

understood by scientists, and research is ongoing in this area, some studies suggest that CBD may have uses in the treatment of seizures and other neurological disorders. A growing number of researchers have expressed interest in conducting research with extracts of marijuana that have a particular percentage of CBD and other cannabinoids.

DEA fully supports research in this area. Based on discussions with NIDA and FDA, DEA has concluded that the best way to satisfy the current researcher demand for a variety of strains of marijuana and cannabinoid extracts is to increase the number of federally authorized marijuana growers. To achieve this result, DEA, in consultation with NIDA and FDA, has developed a new approach to allow additional marijuana growers to apply to become registered with DEA, while upholding U.S. treaty obligations and the CSA. This policy statement explains the new approach, provides details about the process by which potential growers may apply for a DEA registration, and describes the steps they must take to ensure their activity will be carried out in conformity with U.S. treaty obligations and the CSA.

The historical system, under which NIDA relied on one grower to supply marijuana on a contract basis, was designed primarily to supply marijuana for use in federally funded research—not for commercial product development. Thus, under the historical system, there was no clear legal pathway for commercial enterprises to produce marijuana for product development. In contrast, under the new approach explained in this policy statement, persons may become registered with DEA to grow marijuana not only to supply federally funded or other academic researchers, but also for strictly commercial endeavors funded by the private sector and aimed at drug product development. Likewise, under the new approach, should the state of scientific knowledge advance in the future such that a marijuana-derived drug is shown to be safe and effective for medical use, pharmaceutical firms will have a legal means of producing such drugs in the United States—independent of the NIDA contract process.

Legal Considerations

Applicable CSA Provisions

Under the CSA, all persons who seek to manufacture or distribute a controlled substance must apply for a DEA registration. [21 U.S.C. 822\(a\)\(1\)](#). Applications by persons seeking to grow marijuana to supply researchers are governed by [21 U.S.C. 823\(a\)](#); *see generally* [76 FR 51403](#) (2011); [74 FR 2101](#) (2009). Under section 823(a), for DEA to grant a registration, two conditions must be satisfied:

(1) The registration must be consistent with the public interest (based on the enumerated criteria listed in section 823(a)) and (2) the registration must be consistent with U.S. obligations under the Single Convention on Narcotic Drugs, 1953 (Single

Convention). An applicant seeking registration under section 823(a) has “the burden of proving that the requirements for such registration pursuant to [this section] are satisfied.” [21 CFR 1301.44\(a\)](#). Although each application for registration that DEA receives will be evaluated individually based on its own merit, some general considerations warrant mention here.

First, while it is DEA's intention to increase the number of registered marijuana growers who will be supplying U.S. researchers, the CSA does not authorize DEA to register an unlimited number of manufacturers. As subsection 823(a)(1) provides, DEA is obligated to register only the number of bulk manufacturers of a given schedule I or II controlled substance that is necessary to “produce an adequate and uninterrupted supply of these substances under adequately competitive conditions for legitimate medical, scientific, research, and industrial purposes.” See 74 FR at 2127-2130 (discussing meaning of subsection 823(a)(1)). This provision is based on the long-established principle that having fewer registrants of a given controlled substances tends to decrease the likelihood of diversion.

Consistent with subsection 823(a)(1), DEA will evaluate each application it receives to determine whether adding such applicant to the list of registered growers is necessary to provide an adequate and uninterrupted supply of marijuana (including extracts and other derivatives thereof) to researchers in the United States.^[4]

Second, as with any application submitted pursuant to section 823(a), in determining whether the proposed registration would be consistent with the public interest, among the factors to be considered are whether the applicant has previous experience handling controlled substances in a lawful manner and whether the applicant has engaged in illegal activity involving controlled substances. In this context, illegal activity includes any activity in violation of the CSA (regardless of whether such activity is permissible under State law) as well as activity in violation of State or local law. While past illegal conduct involving controlled substances does not automatically disqualify an applicant, it may weigh heavily against granting the registration.

Third, given the in-depth nature of the analysis that the CSA requires DEA to conduct in evaluating these applications, applicants should anticipate that, in addition to the information requested in the application itself, they will be asked to submit other information germane to the application in accordance with [21 CFR 1301.15](#). This will include, among other things, detailed information regarding an applicant's past experience in the manufacture of controlled substances. In addition, applicants will be asked to provide a written explanation of how they believe they would be able to augment the nation's supply of research-grade marijuana within the meaning of subsection 823(a)(1). Applicants may be asked to provide additional written support for their application and other information that DEA deems relevant in evaluating the application under section 823(a).

Treaty Considerations

As stated above, DEA may only issue a registration to grow marijuana to supply researchers if the registration is consistent with U.S. obligations under the Single Convention. Although this policy document will not list all of the applicable requirements of the Single Convention,^[5] the following is a summary of some of the key considerations.

Under articles 23 and 28 of the Single Convention, a party (*i.e.*, a country that is a signatory to the treaty) that allows the cultivation of cannabis for lawful uses (*e.g.*, FDA-authorized clinical trials) must:

- (a) Designate the areas in which, and the plots of land on which, cultivation of the cannabis plant for the purpose of producing cannabis shall be permitted;
- (b) License cultivators authorized to cultivate cannabis;
- (c) Specify through such licensing the extent of the land on which the cultivation is permitted;
- (d) Purchase and take physical possession of all cannabis crops from all cultivators as soon as possible, but not later than four months after the end of the harvest; and
- (e) Have the exclusive right of importing, exporting, wholesale trading and maintaining stocks of cannabis.

As DEA has stated in a prior publication, DEA carries out those functions of article 23, paragraph 2, that are encompassed by the DEA registration system (paragraphs (a) through (c) above), and NIDA carries out those functions relating to purchasing the marijuana and maintaining a monopoly over the wholesale distribution (paragraphs (d) and (e) above).^[6] 76 FR at 51409.

As indicated, DEA's historical approach to ensuring compliance with the foregoing treaty requirements was to limit the registration of marijuana growers who supply researchers to those entities that operate under a contract with NIDA. Under this historical approach, the grower could be considered an extension of NIDA and thus all marijuana produced by the grower was effectively owned by NIDA, with NIDA controlling all distribution to researchers.

However, as further indicated, DEA has concluded, based on discussions with NIDA and FDA, that it would be beneficial for research to allow additional marijuana growers outside the NIDA-contract system, provided this could be accomplished in a manner consistent with the CSA and the treaty. Toward this end, DEA took into account the following statement contained in the official commentary to the Single Convention: Countries . . . which produce . . . cannabis . . . , [i]n so far as they permit private farmers to cultivate the plants . . . , cannot establish with sufficient exactitude the quantities harvested by individual producers. If they allowed the sale of the crops to private traders, they would not be in a position to ascertain with reasonable exactitude the

amounts which enter their controlled trade. The effectiveness of their control régime would thus be considerably weakened. In fact, experience has shown that permitting licensed private traders to purchase the crops results in diversion of large quantities of drugs into illicit channels. . . . [T]he acquisition of the crops and the wholesale and international trade in these agricultural products cannot be entrusted to private traders, but must be undertaken by governmental authorities in the producing countries. Article 23 . . . and article 28 . . . therefore require a government monopoly of the wholesale and international trade in the agricultural product in question in the country which authorizes its production.

Commentary at 278Start Printed Page 53848

Given the foregoing considerations, DEA believes it would be consistent with the purposes of articles 23 and 28 of the Single Convention for DEA to register marijuana growers outside of the NIDA-contract system to supply researchers, *provided the growers agree that they may only distribute marijuana with prior, written approval from DEA*. In other words, in lieu of requiring the growers to operate under a contract with NIDA, a registered grower will be permitted to operate independently, provided the grower agrees (through a written memorandum of agreement with DEA) that it will only distribute marijuana with prior, written approval from DEA. DEA believes this new approach will succeed in avoiding one of the scenarios the treaty is designed to prevent: Private parties trading in marijuana outside the supervision or direction of the federal government.

Also, consistent with the purposes and structure of the CSA, persons who become registered to grow marijuana to supply researchers will only be authorized to supply DEA-registered researchers whose protocols have been determined by the Department of Health and Human Services (HHS) to be scientifically meritorious. See [21 U.S.C. 823\(f\)](#). In 2015, HHS announced the details of its current policy for evaluating the merits of research protocols involving marijuana. [80 FR 35960](#) (2015).

Finally, potential applicants should note that any entity granted a registration to manufacture marijuana to supply researchers will be subject to all applicable requirements of the CSA and DEA regulations, including those relating to quotas, record keeping, order forms, security, and diversion control.

How To Apply for a Registration

Persons interested in applying for a registration to become a bulk manufacturer of marijuana to supply legitimate researchers can find instructions and the application form by going to the DEA Office of Diversion Control Web site registration page at www.deadiversion.usdoj.gov/drugreg/index.html#regapps. Applicants will need to submit Form 225.

Note Regarding the Nature of This Document

This document is a general statement of DEA policy. While this document reflects how DEA intends to implement the relevant statutory and regulatory provisions, it does not establish a rule that is binding on any member of the public. Any person who applies for a registration to grow marijuana (as with any other applicant for registration under the CSA) is entitled to due process in the consideration of the application by the Agency. To ensure such due process, the CSA provides that, before taking action to deny an application for registration, DEA must serve upon the applicant an order to show cause why the application should not be denied, which shall provide the applicant with an opportunity to request a hearing on the application in accordance with the Administrative Procedure Act. [21 U.S.C. 824\(c\)](#).

Start Signature

Dated: July 25, 2016.

Chuck Rosenberg,

Acting Administrator.

End Signature End Supplemental Information

Footnotes

1. There are two FDA-approved drugs that contain a synthetic form of dronabinol, which is one of the chemicals found in marijuana. These drugs are Marinol (which the FDA approved for the treatment of nausea and vomiting associated with cancer chemotherapy, and for the treatment of anorexia associated with weight loss in patients with AIDS) and Syndros (which was approved for the same indications as Marinol).

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2. Funding may actually be the most important factor in whether research with marijuana (or any other experimental drug) takes place. What appears to have been the greatest spike in marijuana research in the United States occurred shortly after the State of California enacted legislation in 1999 to fund such research. Specifically, in 1999, California enacted a law that established the “California Marijuana Research Program” to develop and conduct studies on the potential medical utility of marijuana. Cal. Health & Safety Code § 11362.9. The state legislature appropriated a total of \$9 million for the marijuana research studies. Over the next five years, DEA received applications for registration in connection with at least 17 State-sponsored pre-clinical or clinical studies of marijuana (all of which DEA granted). [74 FR 2101](#), 2105 (2009).

However, it appears that once the State stopped funding the research, the studies ended.

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3. An acceptable and broader definition of “cannabinoids” includes not only those chemicals unique to the cannabis plant but also their derivatives and transformation products.

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4. In making this determination, DEA will consult with NIH and FDA, as warranted.

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5. A detailed explanation of the relevant Single Convention requirements can be found in 74 FR at 2114-2118.

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6. In accordance with the CSA, DEA carries out functions that are indirectly related to those specified in article 23, paragraph 2(e). For example, DEA controls imports and exports of cannabis through the CSA registration and permitting system.

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